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June 14, 2002

VIA MESSENGER
VIA E-mail [quality.guidelines@epa.gov]

Ms. Evangeline Tsibris Cummings
Environmental Protection Agency
Office of Environmental Information
401 M Street, S.W.
Northeast Mall, Room B607
Washington, DC 20460
Attn Docket ID No. OEI-10014

RE: EPA Docket ID No. OEI-10014 - Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency

Dear Ms. Tsibris Cummings:

Please find enclosed the comments of the General Electric Company on the Environmental Protection Agency's Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. 67 Fed. Reg. 21,234 (Apr. 30, 2002).

These comments will be transmitted to you as a PDF document via e-mail and two copies will also be delivered via courier. Please call Cindy Squires at 202-789-6000 if you have any

problem with transmission. Please direct any questions regarding the comments to either Karl Bourdeau at (202) 789-6019 or me at (202) 789-6026.

Sincerely,

Thomas Richichi

KSB:cls
Enclosures

COMMENTS OF THE GENERAL ELECTRIC COMPANY ON THE DRAFT GUIDELINES OF THE U. S. ENVIRONMENTAL PROTECTION AGENCY FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE AGENCY

67 Fed. Reg. 21,234
Docket ID No. OEI-10014

June 14, 2002

INTRODUCTION AND SUMMARY OF COMMENTS

The General Electric Company ("GE") appreciates the opportunity to submit the following comments on the draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. 67 Fed. Reg. 21,234 (Apr. 30, 2002) (hereinafter referred to as "the Guidelines" or "the draft Guidelines" as appropriate to the context of the specific comment).

Congress has directed that broadly applied, comprehensive programs for information stewardship designed to maximize and ensure data quality shall become integral to the mission of all federal agencies, including EPA.[1] The essence of the Congressional mandate is an administrative scheme whose requisite components consist of: (1) statutory standards intended to govern the creation, use and dissemination of quality data by the Agency, (2) the adoption of effective administrative mechanisms to implement those standards, and (3) administrative review that will allow "affected" parties to ensure compliance with those standards by seeking and obtaining timely correction of *all* non-conforming, influential information that is maintained or disseminated by EPA.

As a general matter, GE applauds the fact that both the articulation of EPA's stewardship mission and the Agency's stated commitment to information quality set forth in the draft Guidelines recognize the importance of the quality of information the Agency maintains and disseminates, particularly when matters affecting human health and the environment implicate science considerations. However, the Guidelines need to be significantly revised on seven key

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[1] Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. 106-554 (hereinafter the "Data Quality Act", "DQA", "DQ Act," or the "Act").

issues if the Agency is to achieve the commitment to information quality reflected in its mission statement. Similarly, in a number of important respects, EPA's draft Guidelines unduly limit the scope of the application of the Act, or otherwise fail to meet the purpose and objectives of the DQA and the associated directive from the Office of Management and Budget ("OMB") that established parameters for the adoption of conforming guidelines by each agency.[2]

The following summarizes GE's key concerns and recommendations:

- ***Comment* – *The draft Guidelines should address open issues, limit the caveats and exemptions that undermine the purpose of the Act, and establish a complete, centrally - focused data correction scheme for the Agency.*** Notwithstanding a Congressional mandate to put a functioning system for data correction into place by a date certain, the draft Guidelines appear to have deferred important decisions on a significant number of issues necessary to inaugurate a functioning system. This includes a substantial number of practical and procedural issues related to the operation of the administrative correction mechanism mandated by Congress. In addition, and perhaps more importantly, the draft Guidelines include a variety of broad caveats and sweeping references to potential exemptions that, unless eliminated or narrowly circumscribed, threaten to entirely swallow up the mandate of the Act. The draft Guidelines also lack a centralized focus and commitment to the implementation of new information quality oversight and management systems contemplated by the Act and OMB's Guidelines.

  Recommendation – EPA should revise and reissue or supplement its draft Guidelines to resolve three generic shortcomings that are problematic: (1) the Guidelines must address key open issues identified in these comments; (2) they must circumscribe and limit stated caveats and exemptions including in particular the "adjudication" and "notice and comment" exemptions, which together have the potential to exempt all formal and informal rulemakings, adjudications and remedial decisions; and (3) they must establish a complete, centrally-focused and harmonized data correction scheme to implement new information quality and oversight systems and the administrative correction mechanisms contemplated by Congress and OMB. Specific recommended

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[2] OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8451 (Feb. 22, 2002) ("the OMB Guidelines"). *See also* OMB's June 10, 2002 comments regarding the draft guidelines issued to date by the various agencies, including EPA, entitled "OIRA Review of Information Quality Guidelines Drafted by Agencies." (Hereafter, "the June 10, 2002 OMB Review") (attached as Exhibit A).

measures to address each of these generic issues are set forth elsewhere in this summary and these comments. Concomitantly, EPA should strongly consider providing an additional, subsequent opportunity for further public comment once it has appropriately addressed these open issues, while still meeting the October 1, 2002 deadline for issuing final Guidelines.

- ***Comment* - *EPA should adopt Safe Drinking Water Act standards, including an unqualified and universal commitment to apply best available science with respect to all influential scientific information it disseminates.*** Despite the primacy of scientific information in matters fundamental to EPA's mission of protecting human health and the environment, the Guidelines appear equivocal with respect to the Agency's commitment to the use of the best available science. This lack of certitude is troubling, given that the "best available science" standard already has been adopted by Congress under the Safe Drinking Water Act ("SDWA") as a mandatory requirement for risk assessments, was identified by OMB as the standard of choice in matters involving "influential" scientific information, has been repeatedly acknowledged and applied by EPA as "a core principle" of the Agency, and unquestionably reflects the soundest approach to science policy. Nonetheless, without the benefit of any explanation, the Guidelines indicate that EPA may choose to qualify the use of best available science, with respect to both human health and environmental assessments.

  Recommendation - EPA should adopt the science quality standards set forth in the SDWA. This should include an unqualified and universal commitment to apply the best available science with respect to all influential scientific information it disseminates. The Agency should similarly adopt the SDWA's statutory risk criteria for health assessments and apply them to environmental and ecological assessments.

- ***Comment* - *Requests for information correction should be resolved in a timely fashion using focused procedures in the Guidelines and not be held captive by the rulemaking or other public notice and comment process.*** The draft Guidelines propose to exclude from their purview otherwise appropriate requests for information correction if they also pertain to proposed EPA actions where there will be an opportunity to submit comments. This "exclusion" would improperly exempt from the Data Quality Act the vast majority of regulatory activities in which the Agency engages, due to the current availability of notice and comment for issues ranging from the rulemakings, to guidances, to remediation and permit decisions. Any such approach is not only inconsistent with the objectives of the Act, but also to any EPA actions that must proceed without the benefit of early and timely access to EPA's data correction process.

  Rulemakings (as well as remedial decisions) are often massive undertakings that take years to complete, during which time discrete, easily resolved and/or important data correction requests may languish without response, all the

while adversely affecting the general public and/or the requesting party who is entitled to a timely response under the Act.

Furthermore, the DQ Act itself supports the proposition that "justice delayed is justice denied." The actionable point is the point of dissemination, and the DQ Act provides no exemption for compliance in the case of rulemakings. The Agency's approach here arguably violates the law.

Recommendation – To achieve the purposes of the Act and maximize administrative economies, the Guidelines should be revised to provide that discrete requests for objective information correction are to be resolved in a timely fashion using the focused procedures of the Guidelines, rather than the unwieldy and daunting vehicle of a rulemaking or some other extended Agency decisionmaking process.

- ***Comment*** - ***The draft Guidelines should establish a complete and functional administrative review mechanism.*** The draft Guidelines, by their own admission, have not proposed a complete and functional administrative review mechanism that will afford affected parties a meaningful opportunity to ensure data quality.

  Recommendation – The administrative mechanism set forth in the Guidelines should be made functional and complete by expanding and revising it to include:

  (1) a centralized docket for posting of data challenges, resolutions of those challenges, and uncorrected information found wanting;

  (2) web-based public notification of such challenges and provisions for participation by other affected parties;

  (3) discrete procedures for identifying, holding in abeyance and then correcting "bad" information in accordance with firm Agency deadlines intended to achieve timely review;

  (4) an independent, dedicated appeal board outside the regional and program offices to provide a mechanism for ensuring objective and timely administrative resolution and information correction within the Agency;

  (5) an expedited, interlocutory administrative appeal mechanism that will enable an affected party to compel completion of a review when the Agency fails to act within its own stated timeframes for review, and

  (6) organizational improvements that will better define a centralized, objective, and effective process by which administrative appeals will be pursued within the Agency.

- ***Comment*** **- *The draft Guidelines should more thoroughly describe the considerations that should govern the "quality" of scientific information.*** The draft Guidelines should be revised to expand upon and more appropriately describe the considerations that should govern the "quality" of scientific information, including the statutory standard in the SDWA, the Bradford Hill criteria governing causality,[3] and associated quality considerations derived therefrom. Such an approach is easily articulated, well understood and capable of broad application.

  Recommendations - The Guidelines should approach "quality" information as that which is excellent, complete, up-to-date and accurate. Consistent with that approach, EPA should adopt the statutory standards set forth in the SDWA as the point of departure in the consideration of "quality" with respect to influential scientific information. EPA should also expand upon that standard to provide more specific guidance and identify the following additional factors for inclusion in the Guidelines:

  (1) whether the most accurate methods were used to collect information;

  (2) whether data measurement methodologies were validated;

  (3) whether quality assurance/quality control techniques were applied;

  (4) whether methods used produce data relevant to study hypotheses;

  (5) whether any experimental conditions were carefully controlled;

  (6) whether confounding factors were eliminated or successfully controlled;

  (7) whether covariates were successfully controlled;

  (8) whether the degree and source of measurement variation were determined;

  (9) whether the data were collected by those with requisite qualifications;

  (10) whether study materials/populations were representative of conclusions;

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[3] The Bradford Hill criteria have been recognized by EPA as being determinative of data quality with respect to causality when interpreted in the light of all other information on the agent being assessed. *See* EPA's revised Guidelines for Carcinogen Risk Assessment at 2-7 (July 1999), available at <http://www.epa.gov/ncea/raf/cancer.htm> and 66 Fed. Reg. 59593 (Nov. 29, 2001) (hereafter "EPA's 1999 Draft Carcinogen Guidelines"). Those criteria address temporal relationship, consistency, magnitude of association, biological gradient, specificity of association, biological plausibility and coherence.

(11) whether appropriate statistical methodologies were employed; and

(12) whether weight-of-evidence analysis was applied to the information.

- ***Comment*** **- *EPA should follow the approach taken by other agencies and list specific examples of information products that are representative of identified categories of "influential information."*** The draft Guidelines should be revisited and revised with respect to the issue of what information should be considered "influential." OMB has stated that information is influential if "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." In addition to the classes of information set forth in Section 3.2 of the draft Guidelines that the Agency indicates will generally be viewed as "influential," EPA should identify and list specific examples of information products that are representative of those categories. This will clarify and facilitate the use of the Guidelines both by Agency personnel conducting reviews and potentially affected parties seeking data correction.

  Additionally the Guidelines should be revised to clarify that "affected" persons entitled to invoke the information correction mechanisms are not simply those who may be benefited or injured *per se*, but also those in the private sector or the general public who will be affected with respect to significant decisions and choices they make in their lives and businesses, or the confidence they have in the critical services that government provides and information that they use.

  Recommendations – The Guidelines should incorporate guidance specific to important information products that identifies the following additional categories and types of information as "influential."

  (1) Information contained in EPA's Integrated Risk Information System database ("IRIS");

  (2) Chemical classifications used by EPA (*e.g.*, EPA's list of substances that are persistent, toxic, and bioaccumulative);

  (3) Human health and ecological risk assessment guidelines;

  (4) Major risk assessments likely to have a substantial impact on products;

  (5) Site-specific risk assessments, remedial investigations, feasibility studies and remedial decision documents conducted under RCRA or CERCLA entailing cleanup costs equal to or greater than $25 million;

  (6) Models and "information products" designed to characterize the risks posed by particular facilities, ambient conditions or products (*e.g.*, Risk Screening Environmental Indicators Model);

(7) Tools that rank facilities, entities, organizations, regions, or localities by environmental performance or quality factors;

(8) Information which is intended to, or can reasonably be expected to, influence public opinion;

(9) Information intended to inform or respond to Congress; and

(10) Information obtained from other government sources and relied upon and disseminated by EPA that falls within any of the above categories.

- ***Comment – The Guidelines Should Foreclose the Use of Defective Information Products and Set Firm Deadlines for Timely Review.*** The purpose and objectives of the Data Quality Act will be defeated if EPA does not foreclose the use and dissemination of information determined not to meet the requirements of the Act until such time as that information is corrected.

  Recommendation - The Guidelines should make clear that further use and dissemination of that information by EPA – and by those parties operating under a contract, cooperative agreement, or other such arrangement with the Agency – should be prohibited until the information is corrected. Specifically, EPA should adopt the approach taken by the U.S. Department of the Interior ("DOI") that, if an initial information correction request is determined to be meritorious, the relevant office "*shall* take reasonable steps to withdraw the information from the public domain and from any decision-making process in which it is being used." Moreover, the "[program] office may determine the schedule and procedure for correcting challenged information, but *may not* disseminate the challenged information *in any form* until it has been corrected."

SPECIFIC COMMENTS

I. A Commitment to Information Stewardship is Essential to EPA's Mission

GE commends the discussion of EPA's mission and the statement of its commitment to information stewardship and quality set forth in the draft Guidelines. *See generally* Section 2.[4] That discussion appropriately acknowledges EPA's responsibility to ensure that the information

[4] Unless otherwise apparent from the context in which the term is used, all subsequent references to "Section" refer to the relevant section of the draft Guidelines. Where appropriate, these comments also reference the numbered lines in EPA's draft Guidelines.

it disseminates is, and remains, as accurate, objective and credible as possible. Of particular significance is EPA's recognition that the information that is relevant for purposes of the Guidelines underlies all environmental management decisions and, therefore, "[t]he collection, use, and dissemination of information of known and appropriate quality is integral to ensuring that EPA achieves its regulatory and policy mission." Section 2.2, lines 39-40. Consistent with this acknowledgment, GE agrees that the suitability of program/management data with respect to new, derivative information products is a matter of "paramount importance," particularly given the ever increasing reliance by members of the public, Congress, state and local governments, and the regulated community on the science-driven environmental, health and safety information maintained, used and disseminated by the Agency.

II. The Draft Guidelines Must Address Open Issues, Limit Caveats and Exemptions, and Establish a Complete, Centrally Focused Data Correction Scheme for the Agency

A. Congress Has Required EPA to Establish a Comprehensive System for Information Quality Management and Assurance that Allows Affected Parties to Ensure Compliance with Data Quality Requirements Through Meaningful Administrative Review.

The Guidelines were mandated by Section 515 of the Act and its associated directive to OMB to require all federal agencies to develop and implement conforming "guidelines" consistent with the language and purpose of the Act, as well as OMB's February 22, 2002 publication in the Federal Register.[5] A fair reading of the Act reveals the Congressional mandate to be comprised of at least two essential components relative to the Guidelines.

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[5] GE submitted comments on October 26, 2001 on the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Dissemination by Federal Agencies, as originally issued by OMB on September 28, 2001 (66 Fed. Reg. 49,718). GE's comments on those OMB guidelines are attached as Exhibit B hereto and hereby incorporated by reference. In the event of any inconsistencies between those comments, which
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First, Congress stated that, by a date certain,[6] EPA (and other agencies) must ensure that their maintenance and dissemination of information is based on application of express standards of "quality, objectivity, utility and integrity" as set out in the Act. As a logical corollary of this requirement, EPA must take affirmative steps to incorporate internal, pre-dissemination procedures and review mechanisms to ensure that newly generated information meets those standards. Consistent with a recognition of this obligation, the draft Guidelines state that EPA's offices and regions are to incorporate the information quality principles into their pre-dissemination review procedures.[7] At the same time, because *existing* information products are among those that will be maintained and disseminated by the Agency after October 1, 2002, it is apparent that the Agency will also have to identify and correct such information to the extent it does not meet these quality principles.[8]

Second, Congress authorized OMB to require EPA to develop and implement certain administrative review mechanisms that would afford affected persons *outside* of EPA the opportunity "to seek and obtain correction of information maintained and disseminated by the Agency." DQA, Section 515(b)(2)(B). On its face, this provision of the Act appears intended to

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were prepared prior to issuance of the draft Guidelines, and these comments on the draft Guidelines themselves, the latter should control.

[6] OMB issued its guidance on September 28, 2001 and in accordance with Section 515 of the Act, EPA's conforming Guidelines must become effective one year thereafter, *i.e.*, October 1, 2002.

[7] Unfortunately, while recognizing the obligation to provide for pre-dissemination review, as discussed later in these comments, the draft Guidelines essentially fail to explain what that review should entail. Moreover, the interests of consistency, transparency and timely implementation of the Act would be best served by a more harmonized approach that did not foster the Balkanization of pre-dissemination review by abdicating and dispersing the task of defining its essential aspects to a host of regional and program offices.

[8] This interpretation is supported by OMB in its discussion of the "Effective Date" in the June 10, 2002 OMB Review.

accomplish two objectives – public oversight of EPA's compliance with the new quality standards for information dissemination and maintenance and, with respect to individuals, the actual correction of incorrect information that might adversely affect them. *See* DQA, Section 515(a), (b)(2)(A)-(B).[9]

In sum, Congress has required EPA to establish a comprehensive, functioning system for information quality management and assurance that must have as an essential element the opportunity for affected parties to participate and ensure compliance with the data quality requirements through meaningful administrative review mechanisms. Thus, the requirement is not only to assure upfront, organic quality control by the Agency, but also to provide for information correction and oversight by the affected public.

B. The Draft Guidelines Largely Disregard Both Components of this Congressional Mandate with Respect to Pre-Dissemination Information Quality Policies and Procedures

Notwithstanding these directives, the draft Guidelines largely disregard both of these components of the Congressional mandate. For example, the draft Guidelines seem to approach the Act more from the perspective of a survey of its existing data quality policies than as an opportunity to implement institutional improvements. While this policy survey provides some informative context and is useful in certain respects, it also appears to ignore the need for the adoption and incorporation of new, additional measures to implement a more functional,

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[9] As explained in the June 10, 2002 OMB Review (Section V, "Affected Person") and discussed later in these comments, this provision should be applied "broadly" to "ensure full public access" to the process.

comprehensive and complete scheme for ensuring data quality.[10] That such new measures are necessary was acknowledged at EPA's May 15, 2002 public hearing on the draft Guidelines, where the Agency's Assistant Administrator of the Office of Environmental Information herself pointed out that EPA has significant data quality problems because, inter alia, much of the information it maintains and disseminates is outdated and there is no effective process for assuring its accuracy, correction or removal.[11]

Yet, the draft Guidelines, taken as a whole, do not appear intent on institutionalizing improved practices, procedures and standards. Rather than propose a new, comprehensive and uniform Agency-wide approach to information policy and its implementation, they instead suggest a potentially disjointed, internally inconsistent and balkanized effort revolving around yet-to-be developed policies and procedures that are to come from the program offices and regions through some yet to be defined process.[12] Unfortunately, the Guidelines thereby miss the opportunity provided by the Act and OMB's Guidelines to establish a comprehensive, centralized information management system, define specific Agency roles and responsibilities, outline and establish protocols for communication and dispute resolution, and set timeframes for

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[10] In this regard, OMB has emphasized that "a mere description of current practices . . . is not a substitute for explicit performance goals." *See* the June 10, 2002 OMB Review, Section III (Agency Commitment to Information Quality Standards").

[11] Indeed, the need for EPA to develop and implement new information quality policies and procedures, rather than merely rely on existing ones, is evident by passage of the Data Quality Act itself. Had Congress been satisfied with existing information quality mechanisms of federal agencies, there would have been no need to enact the DQA.

[12] For example, Section 5.7 of the draft Guidelines places responsibility for correction of information in the offices and regions under review procedures to be developed by Assistant Administrators or Regional Administrators. In addition to being inconsistent with OMB's directive that a decision on appeal come from outside the office or region that disseminated the information in the first instance, the draft Guidelines are completely silent with respect to what review procedures the regions will apply, how consistency will be ensured between regions, and when those procedures will be available for comment.

action and implementation of specific pre-dissemination review procedures and policies. For example, rather than making a wholesale delegation of responsibility for information correction to the program offices and regions, EPA should focus on an scheme developed and managed by a central authority within EPA Headquarters that has responsibility for adopting and ensuring the implementation of uniform, detailed and consistent substantive and procedural requirements for ensuring data quality Agency-wide.

In addition, the draft Guidelines include a number of broad, open-ended caveats and exceptions that threaten to undermine the purpose of the Act and the Guidelines. For example, EPA states in Section 1.1, lines 404-406, that it will feel free to disregard the Guidelines (and hence, the Act itself) "on a case-by-case basis," without explaining why and under what specific circumstances it believes it would have the authority to do so. Obviously, a wholesale disregard of the Guidelines in a given situation could violate the fundamental Data Quality Act requirements, both substantive and procedural. This open-ended exception should be deleted to ensure meaningful future compliance with the Data Quality Act.[13]

Similarly, Section 5.5, lines 760-762 of the draft Guidelines states that EPA may simply decide not to correct information products due to Agency "priorities" or "time constraints," again not providing any explanation or rationale as to why or when it would take such an approach (or how that approach accords with the Act's mandate that nonconforming information be corrected in a timely fashion). Neither the Act nor the OMB Guidelines provide for such an exemption and accordingly, it should be deleted.

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[13] Indeed, GE submits that EPA does not have the authority to exempt any influential information it disseminates from the requirements of the Act.

Section 1.3 of the draft Guidelines also raises serious concerns with respect to certain types of information that EPA indicates would not be considered to be "disseminated" for purposes of review. Accordingly, GE offers the following comments:

- **Adjudicative Proceedings** - OMB has specifically admonished EPA and other agencies not to broaden the exception for "adjudicative proceedings" beyond the intent of OMB Guidelines. *See* the June 10, 2002 OMB Review. OMB's Guidelines state that this exception is *only* intended to address "the findings and determinations that an agency makes in the course of adjudications involving specific parties." 67 Fed. Reg. at 8454. Moreover, as OMB has explained, the exception for adjudications is intended to apply only in adjudicative "proceedings" that afford parties the *opportunity to contest decisions.*[14] EPA, however, has unnecessarily expanded the description of such adjudications beyond the intent of OMB Guidelines. Accordingly, as OMB has directed, the Agency should carefully limit this exception to be consistent with OMB's Guidelines both (1) "as to the adjudicative *procedures* that are included," and (2) "the *scope* of information covered." *See* the June 10, 2002 OMB Review, Section 1. GE suggests that the most appropriate approach for doing so would be for EPA to simply adopt the language of the OMB Guidelines.

- **Research Funded by EPA** - The Guidelines should make clear that they are applicable to any document used in support of, and disseminated in connection with, other information released by the Agency even if such documents are not "authored" by EPA. Documents representing research or science supported by EPA funding should be subject to the Guidelines if the information is being developed by a recipient of a federal grant and (i) the Agency "represents the information as, or uses the information in support of, an official position of [EPA]";[15] or (ii) the recipient of the grant is collecting the information at the specific request of EPA, or (iii) the terms and conditions of the grant require approval by EPA of the collection of information or collection procedures.[16]

- **Press Releases** - With respect to press releases, the Guidelines should clarify that a categorical exclusion of them is not appropriate. Such announcements (and any accompanying "Fact Sheets") often constitute the first (or early) dissemination by EPA of important determinations or findings it has made. They also can seek to

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[14] In order to serve as a meaningful alternative to the DQA, the opportunity to "contest a decision" also must be provided in a timeframe commensurate with the Act.

[15] 67 Fed. Reg. at 8453.

[16] *See* 5 C.F.R. § 1320.3(d)(1),(2) (defining when information collected by a recipient of a federal grant is considered "conducted or sponsored" by a federal agency).

influence public opinion by trying to persuade readers of the force behind the Agency's actions. As such, these announcements should constitute "information disseminated" by EPA and be covered by the Guidelines,[17] unless the Agency can demonstrate that they are derivative of and co-extensive with information that has already been subject to the requirements of the Act.[18]

C. The Draft Guidelines Obscure and Diminish the Public Oversight and Administrative Correction Aspects of the Act With Respect to Post-Dissemination Information

Although EPA is expressly required to develop and implement administrative correction and appeal procedures that will enable affected entities outside the Agency to seek and obtain timely data correction,[19] the Agency has approached the draft Guidelines in a manner that minimizes the importance of outside review,[20] saddles it with an incomplete and incomprehensible working framework,[21] and unduly qualifies it with confusing and otherwise unnecessary disclaimers.[22] Such an approach appears at odds with the proffered mission

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[17] The same is true for "distribution of information limited to correspondence with individuals or persons," as such correspondence often disseminates information that affects the interests not only of the recipient(s) but others as well. *See* U.S. Dept. Health and Human Services Draft Implementation Plan ("draft HHS Plan") Part I, Section D.3.) available at <http://www.hhs.gov/infoquality/toc.htm> .

[18] This position is consistent with the views expressed in the June 10, 2002 OMB Review where it has indicated that press releases and fact sheets may not be subject to the requirements of the Act, *provided* that they reflect information already disseminated and subject to the requirements of the Act.

[19] *See* Section 515(b)(2)(B) of the Act.

[20] *See, e.g.,* Section 4.5 of the Background and Discussion (Complaint Resolution) where EPA suggests that the existing Integrated Error Correction Process is sufficient to ensure a timely and appropriate response to data quality complaints.

[21] *See, e.g.*, Section 5.5 of the Guidelines ("How Will EPA Respond to a Request for Correction of Information") in which the text effectively says nothing more about the decision making process than, "[i]f a request for correction is deemed appropriate ... EPA will make a decision."

[22] In its statement of purpose, the Agency has included boilerplate language to the effect that the Guidelines do not create any rights or requirements that bind the Agency. *See* Section 1.1. Courts have been critical of such boilerplate language when it attempts to recast the actual import of Congressional or agency action (*see, e.g., Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-1024 (D.C. Cir. 2000)) and, indeed, the Guidelines would appear to be at odds with plain meaning of the Act on this point. By including that language in the draft Guidelines

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statement and sends a signal to those inside and outside the Agency that EPA is not serious about data quality issues. Moreover, it minimizes the important role that Congress envisioned for those affected members of the general public and the private sector in monitoring, identifying, informing and ensuring compliance with the data quality requirements of the Act.

Indeed, OMB has raised the same concerns. For example in its June 10, 2002 Review commenting on draft agency guidance, OMB stated that regardless of what disclaimers agencies choose to include in their guidelines, they "should not suggest that [they] are free to disregard their own guidelines." Section V. Similarly, agencies should not suggest that the "agency information quality standards are not statements of government-wide policy," or that "an agency is free to ignore [such standards] . . . based on unspecified circumstances." *Id.*

Finally, despite a Congressional mandate and a specific directive to EPA to implement a comprehensive functional program to examine information quality by a date certain, the Agency has deferred addressing key substantive and procedural decisions related to the administrative correction mechanisms mandated by Congress. This deferral extends, for example, to such matters as the specific elements of the appeals process, timeframes for submissions and replies, administrative record and other procedural elements and requirements, timeframes for resolution of information correction requests and administrative appeals, and mechanisms for ensuring timely correction of information determined to be non-compliant with the OMB or EPA guidelines. EPA's ambiguity about when those mechanisms will be effectuated and the specifics

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EPA creates unnecessary confusion regarding whether affected entities can look to the Guidelines as a mechanism to vindicate their statutory rights to information quality and correction.

of how they will function has had the practical effect of severely limiting the opportunity for effective notice and comment on them.

III. Consistent with Administrator Whitman's Stated Commitment to Best Available Science EPA Should Adopt, Rather than Adapt, Safe Drinking Water Act Standards, Including an Unqualified and Universal Commitment to Apply Best Available Science With Respect to All Influential Scientific Information It Disseminates

Perhaps as much as any other agency, scientific information proves most critical to the accomplishment of EPA's mission. Increasingly, the scientific information developed, maintained, used, and disseminated by the Agency also proves to be the type of information that is relied upon and governs the affairs of the public, private and governmental sectors. Such information, either directly or derivatively, drives public and private perceptions of issues, dictates commitment of substantial public and private resources, and has become a paramount consideration in the decisions and choices that are made in all matters that involve human health and the environment. Thus, the quality of EPA's science information and analysis is vital to the credibility of EPA decisions, the encouragement of further scientific research, and the promotion of public confidence in the wisdom of decisions based upon such information and analysis. Reliance upon sound science is, as the Administrator has explained, the most appropriate and effective approach to achieving reasonable, consistent, and health-protective decisions about exposures to environmental hazards.[23]

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[23] *See, e.g.,* April 10, 2001 Memorandum re "EPA's Regulatory Decision Process and Innovation Strategy" from Administrator Whitman to the Assistant Administrators, General Counsel, Inspector General, Chief Financial Officer, Associate Administrators, Regional Administrators and Staff Office Directors; Statement of Administrator Christine Todd Whitman (EPA Science Forum, May 1, 2002 ("I firmly believe the credibility of our decisions depends on the science underlying them.... To make decisions based on sound science, policymakers need information that reflects the *latest findings in high quality research* and analyses."); Statement of Christine Todd Whitman, nominee to be Administrator of EPA, Senate Committee on Environment and Public Works (January 17, 2001) ("Scientific analysis should drive policy. Neither policy nor politics should drive scientific results.")

A. EPA Should Adopt an Unqualified and Universal Commitment to the Use of the Best Available Science with Respect to all influential Scientific Information it Disseminated

The Guidelines should leave no doubt that EPA is unequivocally committed to the use of the "best available science" in ensuring the quality and objectivity (*i.e.*, the accuracy, reliability, and impartiality) of scientific information. The rationale supporting such a commitment is compelling for several reasons. First, the use of the "best available science" represents a standard that has been sanctioned by Congress and enacted into law . In that regard, the Safe Drinking Water Act ("SDWA") expressly provides that, "*to the degree that Agency action is based on science,*" EPA "shall use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and "data collected by accepted methods or best available methods." 42 U.S.C. § 300g-1(b)(3)(A) (emphasis added).[24]

Furthermore, EPA has consistently identified its adherence to the use of best available science as "a core principle" of the Agency. *See, e.g.*, 63 Fed. Reg. 69,389, 69,401 (Dec. 16, 1998). Indeed, it has applied that core principle in numerous rulemakings and risk assessments undertaken pursuant to the SDWA and should therefore possess the requisite experience to adopt and apply it in the broader context of the guidelines.

Finally, OMB has urged each agency in developing its Guidelines to consider adopting these basic Congressional standards as appropriate for judging the quality of disseminated

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[24] Congress has decided that the standard for the dissemination of information under the DQA should be "quality." Given that Congress mandated quality as a fundamental standard, OMB apparently looked to instances where Congress had addressed the "quality" of scientific information in the past to identify an appropriate "basic standard of quality." *See* 67 Fed Reg. at 8457. In this regard, it is significant to note that the legislative history of the SDWA states that Congress concluded that "the quality of science" needed improvement, hence the adoption of the "best available science" standard. S. Rep. No. 104-169, at 17 (1995).

scientific information. Indeed, common sense and the collective wisdom of the scientific community make it difficult to conceive of any scenario under which EPA would not want to adopt a standard for important human health or environmental information that is based upon the concept of using the "best available science."

In view of these factors, it is somewhat perplexing that while EPA has affirmed its commitment to the basic SDWA quality standards in the draft Guidelines, it has also stated that it will merely "adapt", rather than "adopt", the SDWA language and apply it only "as appropriate." GE believes there is no good reason to ignore fundamental common sense and the prevailing collective wisdom of Congress, EPA and the scientific community to the effect that the wholesale *adoption* of use of "best available science" by the Agency as a quality standard is in the public interest. Indeed, it is *never* appropriate to disregard the best available science.[25]

B. The Guidelines Should Adopt the SDWA Standards with Respect to Health Risk Assessments

Similarly, in matters involving risks of adverse health effects, the Guidelines should adopt the well-founded SDWA standards. These standards, which have been widely applied and acknowledged as appropriate standards, require the presentation of information (i) to be "comprehensive, informative and understandable," and (ii) specify to the extent practicable in the case of scientific information made available in support of a regulation:

- each population addressed by any estimate of public health effects risks;

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[25] GE recognizes that "peer-reviewed" studies may not always be available. If this is a consideration in the Agency's approach to the SDWA standard, the Guidelines should clarify that point. *See* the June 10, 2002 OMB Review (Agencies need to "clearly state that they are adopting the SDWA standards, or justify in what ways and for what kinds of information the agency is adapting the SDWA standards.") In this regard, the most appropriate approach would be for the Guidelines to expressly adopt the SDWA statutory language for purposes of defining "quality" for the entire category of "influential scientific and statistical information," and if necessary, simply explain that peer-reviewed evidence may not always be available.

- the expected risk or central estimate of risk for the specified populations;
- each appropriate upper-bound and lower-bound estimate of risk for the specified populations;
- each significant uncertainty identified in the process of the assessment of public health effects risks and studies that would assist in resolving the uncertainty; and;
- peer-reviewed studies known to EPA that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. 300g-1(b)(3)(B).

Moreover, EPA should make clear that these standards will apply to *all* health risk assessment information made available to the public, not just documents related to rulemaking. Significantly, after careful and thorough consideration, the Food and Drug Administration has already decided that the SDWA standards should apply to all health risk assessments disseminated to the public and, in fact, OMB has identified that decision as "the proper approach." *See* the June 10, 2002 OMB Review, Section III ("Analysis of Risks in Human Health, Safety and the Environment").

C. The SDWA Risk Assessment Standards Should be Applied to Ecological Risk Assessments

EPA has asked for comment on the issue of whether it should also apply the SDWA risk assessment standards to the use of science in contexts other than "influential" human health risk assessments, *e.g.*, to situations involving ecological risk assessments. *See* Section 3.4. GE believes that these SDWA health risk standards also provide a "basic quality standard" that can be readily applied with respect to environmental and ecological risk assessments and urges EPA to take such an approach in the Guidelines. As noted, these standards are grounded in sound science and the Agency has sufficient experience in applying them that this objective could be

easily achieved to provide additional, meaningful assurances of data quality in the context of environmental assessment.

Such an approach should be premised on several key principles. First, it is well accepted that ecological risk assessments should focus on evaluating potential adverse effects or risks to local *populations and communities* of biota -- as opposed to *individual* organisms -- because the goal of remedial actions is to protect such local populations and communities. *See, e.g.*, EPA, *Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites,* OSWER Directive 9285.7-28 P (October 7, 1999) at pp. 3 & 5.

Second, although, it might appear that threatened and endangered species represent an exception to this rule, the reason that such species may be evaluated on a more individual basis is that, given the stressed nature of the population, effects on individuals could have a significant impact on the local population. Thus, endangered species do not, in fact, represent an exception to the general rule.

Third, ecological risk assessments can include a wide range of studies, including literature-based studies, modeling, laboratory studies, and field studies. In this regard, *site-specific studies* that directly evaluate the health and sustainability of the actual local populations and communities of the biota involved should *generally be preferred over non-site-specific* studies, such as literature-based analyses and laboratory toxicity tests. *See, e.g.*, OSWER Directive 9285.7-28 P at p. 3 (site-specific data should be collected and used, where practical, in ecological risk assessments). This is because literature-based analyses and laboratory studies may be based on non-site-specific species and cannot take into account density-dependent and other natural mechanisms that may control actual field populations of the biota (regardless of the

chemical exposure). Hence, there is inherently much more uncertainty in any attempt to extrapolate from them to predict actual effects on the local populations.

Finally, it is well-accepted in ecological risk assessment that the results of the various lines of evidence developed for each receptor group should be evaluated on an overall basis to determine the potential for adverse impacts to the local population of that receptor group. *See, e.g.*, EPA, *Guidelines for Ecological Risk Assessment*, EPA/630/R-95/002F (April 1998) at pp. 103-105. In other contexts, EPA has supported the use of a weight-of-evidence approach to evaluate such multiple lines of evidence. *See, e.g.*, EPA's 1999 Draft Carcinogen Guidelines. Further, EPA recognizes that "evidence of causality is key to the risk assessment," and that thus "it is important to evaluate the strength of the causal association between site-related contaminants and effects on the . . . endpoints [involved]." EPA, *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*, EPA 540-R-97-006, OSWER 9285.7-25 (June 1997) at p. 6-4.

Given the above, a *weight-of-evidence assessment should be conducted* that focuses on the extent to which, *using accepted causation principles*,[26] exposure to the chemical(s) being assessed will cause adverse impacts or risks to the local population or community. Such an assessment systematically examines the strengths and weaknesses of each study. Consistent with this, in considering these factors, well-conducted field studies that directly evaluate the health or sustainability of the local population or community should be given more weight than non-site-specific literature-based or laboratory studies.

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[26] *E.g.*, the Bradford Hill Causation criteria. *See* note 3 above.

D. The Best Available Evidence Standard Should Apply at the Time Information in a Risk Assessment is Disseminated

GE notes that under the draft Guidelines, "best available" refers to availability at the time any risk assessment is made, rather than when the information is finally disseminated. Under this approach, EPA could ignore new "best science" that becomes available between the time EPA proposes a regulation (or remedial decision) based on a risk assessment and the time it finalizes that regulation (or other decision) based on that original, now flawed assessment. This result is inconsistent with the fundamental premise of the DQA and OMB guidelines that *all* information disseminated by the Agency should reflect basic quality standards.

It is also at odds with the purpose of a risk assessment, which is to provide an accurate appraisal of the science that will inform public health decisions. *See* EPA's 1999 Draft Carcinogen Guidelines at 5.1 (Purpose). If the science that formed the basis for the appraisal was flawed and has since been corrected, the only appropriate course of action under the DQA (or otherwise), is to ensure that the risk assessment that is disseminated reflects a *new* appraisal consistent with correct science. Accordingly, EPA should revise its Guidelines to ensure that it is clear that "availability" refers to "availability" at the time of information dissemination.[27]

IV. Requests for Information Correction Must Be Resolved in a Timely Fashion Using Focused Procedures in the Guidelines and Not be Held Captive by the Rulemaking Comment Process

The draft Guidelines propose to exclude from their purview otherwise appropriate requests for information correction if they also pertain to EPA actions where there will be an

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[27] GE recognizes that EPA has a legitimate interest in bringing "finality" to its decision making processes. The Agency can adequately serve that interest, however, by (i) limiting post-proposal requests to use new "best available science" to those for which the grounds arose after the Agency's proposal of an action, and (ii) using, as it does now, "notices of data availability" that expedite comment on, and response to, newly furnished information.

opportunity to submit comments. Section 5.4, lines 738-740. Unfortunately, such an approach will not only violate the terms of the Act, but will also (i) be wasteful of public and private resources in the case of EPA actions that will have to proceed through their course without the benefit of EPA's early data correction process, and (ii) in the vast majority of the agency's regulatory activities, including rulemakings, guidances, and RCRA and Superfund remediation and risk assessment activities, deprive affected parties of their statutory right to timely resolution of information correction requests. For these and other reasons discussed below, GE believes such an approach is highly problematic and should be withdrawn.

Rulemakings (and remedial decisions) implicating scientific information are often massive undertakings that take years to complete. During that time, it is quite likely that discrete and easily resolved data correction requests may languish without the benefit of any response under the draft Guidelines. Prior to a response to comments in the final rulemaking package or the judicial review, post-enforcement of a Superfund Record of Decision and associated documents, the offending flawed information could continue to adversely affect a requesting party and a large universe of communities or other affected parties, notwithstanding the fact that these parties would otherwise be entitled to a timely response under the Act.

On the other hand, more substantive and difficult information correction requests may also be made in the context of such proposed Agency actions. Unless those requests are resolved early in the course of the decisionmaking process, the Agency and interested stakeholders may expend considerable resources on other elements of the Agency action in question only to find that their efforts were for naught because the rulemaking or remediation was predicated on faulty information.

Similarly, rulemakings, remediations or other agency actions may turn on the consideration of a wide range of cumulative scientific evidence that ultimately may render it unnecessary to address an affected party's data correction request to reach a decision. For example, it is reasonable to expect that parties with absolutely no interest in a particular rulemaking may have an interest in pursuing discrete correction requests involving information that only coincidentally may be part of the rulemaking record.[28] In such circumstances, the party's real concern is not the rule, but the adverse effect the erroneous or outdated information has upon them in another, unrelated context (*e.g.*, business reputation or tort liability). Nonetheless, their injury and the intent of Congress to afford an opportunity to resolve it will be held captive by the rulemaking.[29]

Finally, resolution of information correction requests through response to comments on proposed EPA actions places those decisions in the hands of the very Agency officials who proposed use of the information in the first place. As discussed further below,[30] that result is flatly inconsistent with the OMB Guidelines, which direct that affected parties are to have the right to administrative appeals decided by an office other than the one originally responsible for

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[28] *See* the June 10, 2002 OMB Review, Section VI, explaining that in the context of a particular agency policy decision, a possible complaint under the DQA may have an interest in a study, but not necessarily in the substantive policies embarked in the rulemaking. The possible complaint may only learn that the agency has disseminated the study after the comment period has expired.

[29] The June 10, 2002 OMB Review recognizes that a timely response to data correction will not occur if a rulemaking will take a disparate length of time to be concluded. Section VI.

[30] GE's comments on the administrative correction mechanism further highlight this important point that was expressed in the OMB Guidelines, *i.e.*, that the interests of objectivity and public confidence in the review process require that a decision on appeal in a data quality challenge come from outside the office or region that disseminated the information in the first instance. 67 Fed. Reg. at 8458.

disseminating the information. *Accordingly, GE urges EPA to eliminate this categorical exception to use of the information correction request and appeal mechanisms of the Guidelines.*

In any event, irrespective of any action taken with respect to an information product in the context of a particular rulemaking (or other proposed Agency action), any affected party should be able to request subsequent correction of that information product if new science material to its continuing validity develops. While the Agency may take reasonable steps to ensure that the request is not made in such a manner so as to prevent closure with respect to EPA's response to comments, ultimately the Agency should base its willingness to consider a new request based on the power of the new information that provides the basis for the request (whether that request occurs prior or subsequent to the conclusion of an Agency rulemaking or other action). In this regard, information should be viewed as accurate, reliable and objective based on empirical considerations, rather than when the information came to light.

V. Additional Considerations with Respect to the Definition of "Quality"

A. The Draft Guidelines Should More Thoroughly Describe the Considerations that Govern the "Quality" Of Scientific Information

Section 515 of the Act requires OMB to issue guidelines to federal agencies requiring them to issue their own guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency." As suggested by OMB's Guidelines, taken together, these qualitative principles define a minimum standard for federal agencies to ensure and maximize data quality. Moreover, it stands to reason that, in identifying these factors individually, Congress obviously intended that each of them was essential to achieving the purposes of the Act.

GE generally concurs with the qualitative definition of "quality, objectivity, utility and integrity" set forth in the draft Guidelines. For example, it is appropriate to define quality to

include objectivity and integrity. It is also appropriate to define objectivity, as the Guidelines do, in terms of whether the information is presented in an accurate, clear, complete and unbiased manner, and as a matter of substance is accurate, reliable and unbiased.

Furthermore, as previously explained, GE believes that the point of departure in the consideration of "quality" with respect, at the very least, to influential scientific information should be the statutory standard set forth in the SDWA. Such a starting point is easily articulated, well understood and capable of broad application, while at the same time entirely consistent with the mandate of Section 515 that EPA "ensure and maximize the quality" of scientific information disseminated by the Agency. However, it is also reasonable to expand upon that standard to provide more specific guidance and to improve the Agency's pre-dissemination review procedures. In that regard, GE recommends that EPA consider identifying the following additional factors for inclusion in the Guidelines:

(1) whether the most accurate and precise methods available were used to collect the information;

(2) whether data measurement methodologies were validated;

(3) whether quality assurance/quality control techniques were applied;

(4) whether the method used will produce data that are relevant to evaluating the hypothesis of the study;

(5) whether any experimental conditions were carefully controlled;

(6) whether confounding factors were eliminated or successfully controlled;

(7) whether covariates were successfully controlled;

(8) whether the degree and source of variation in measurement were determined;

(9) whether the data were collected by individuals with the qualifications and experience required given the nature of the data;

(10) whether study materials/populations were representative given the conclusions drawn from the study;

(11) whether appropriate statistical methodologies were employed; and

(12) whether weight-of-evidence analysis was applied to the information.

Moreover, in the area of scientific information, it is important to distinguish between agency dissemination of the results of an individual scientific or statistical study, and an agency's evaluation, recommendation or decision based on the agency's analysis and synthesis of a *number* of scientific or statistical studies. Although data quality requirements for "influential scientific and statistical information" are to be applicable to reviews of the individual studies consulted in the course of an agency's assessment, much more should be required of the Agency's assessment as it brings the force of its power and influence to the conclusions of the evaluation, recommendation or decision.

In view of this, dissemination of an agency evaluation, recommendation or decision based on the agency's analysis and synthesis of a number of scientific or statistical studies should only occur after: (1) the analysis and synthesis has been conducted consistent with the "weight-of-evidence" approach[31] or, if applicable, "causation analysis" based upon the Bradford

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[31] Synthesizing the results of a number of scientific studies whose findings are not entirely consistent requires application of the weight-of-evidence approach. Such an approach assists the decision maker in organizing and sorting through scientific findings that may appear to conflict and provides a reasoned and rational framework for both making and presenting decisions. The weight-of-evidence approach involves careful and thorough review of study methodologies and results, as well as assessment of the relative weights that should be given to the results of individual studies or groups of studies. Thus, the importance that should be given to a particular study depends both on the quality of the study and its relevance to the issue being analyzed. Quality is assessed using the referenced principles and the factors set forth above in the text, *i.e.*, method accuracy, precision and validation; quality assurance/quality control; control of experimental conditions; confounding factors and covariates; representativeness of study materials/populations; and appropriateness of statistical methodologies employed.

Hill criteria,[32] and (2) a full and fair peer review of the weight of evidence/causation analysis has been conducted.

With respect to the latter, it is important to note that use of such a weight of evidence and causation analysis is consistent with, if not mandated by, the Safe Drinking Water Act principle requiring consideration of "peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data." 42 U.S.C. § 300g-1(b)(3)(B)(v). Moreover, to ensure that the peer review is full, fair and objective, the Guidelines should provide that the charge made to any peer-review panel should be made available for public comment.[33]

B. EPA Should Propose for Comment Specific Policies and Procedures for Enhanced Pre-Dissemination Data Quality Review that Build Upon the Lessons EPA Has Learned as a Result of the Shortcomings in Its Current Information Development and Dissemination Systems

It is likely to be more efficient and effective to ensure that EPA employs "sound science" in the first instance than to correct non-compliance with DQA requirements after the fact. It is imperative, therefore, that the Guidelines focus on pre-dissemination review as well as administrative review. Indeed, such a requirement is an obvious element of the approach mandated by Congress in the Act, as evidenced by OMB's statement that as a matter of good and

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[32] Causation analysis is a type of weight-of-evidence assessment of particular utility in determining whether there is a causal relationship between events or circumstances that have been found to be associated. The Bradford Hill criteria provide explicit guidance for evaluating such causal relationships. *See* note 3 and Exhibit C.

[33] The Guidelines reference EPA's peer review policy, "Peer Review and Peer Involvement at the U.S. Environmental Protection Agency" (June 7, 1994). Nevertheless, they should also emphasize that peer reviews be "full" and "fair" and viewed as an important part of the decision making process, rather than a bureaucratic exercise. Assessments of EPA peer review by the National Research Council ("NRC") and the EPA Science Advisory Board ("SAB") in the past have raised important issues related to the use of selective inquiries and failure to assure that peer reviewers are unbiased.

effective agency information resources management, agencies shall develop "procedures for reviewing and substantiating . . . the quality (including the objectivity, utility, and integrity) of information *before* it is disseminated."[34]

The fact that agencies must treat information quality as integral to every step of their development of information, including creation, collection, maintenance, and dissemination, is fundamental to achieving the purposes of the Act. It is also critical for building a record that will facilitate subsequent review while minimizing unnecessary demands on Agency resources. Accordingly, the data generation process required of agencies must be trustworthy and robust in the first instance if the Act is to achieve its purposes.

Unfortunately, the draft Guidelines are largely silent on how pre-dissemination review will be improved upon and facilitated going forward.[35] This omission is particularly disappointing in that the Agency has previously developed a framework for an institutional approach that contemplates design, development, review, dissemination, maintenance and feedback.[36] GE views this result as a missed opportunity to solicit useful feedback from stakeholders going to such a framework, and to improve information stewardship generally.

Accordingly, EPA should either include in the Guidelines or propose for further comment before October 1, 2002 specific policies and procedures for enhanced pre-dissemination data quality review that build upon the lessons EPA has learned as a result of the shortcomings (acknowledged by the Agency itself) in its current information development and dissemination

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[34] 67 Fed. Reg. at 8453 (emphasis added).

[35] The draft Guidelines contain only two sentences on the pre-dissemination process. *See* Section 4.1, lines 698-701.

[36] *See* "Lessons Learned about Designing, Developing and Disseminating Environmental Information Products," Office of Environmental Information (260R-00-001) (November 17, 2000).

systems. As part of this effort, EPA should carefully review its existing data quality tools and fashion them into a more robust, fully harmonized pre-dissemination review process across the Agency consistent with intent of the DQA. Among the existing tools it should look to and apply in developing their robust process is the "EPA Quality Manual for Environmental Programs 5360 A1" (May 5, 2000) ("EPA Quality Manual"). Consistent with the latter, the draft Guidelines should specifically incorporate requirements for quality procedures including: (1) an updated statement of quality system policy and rationale reflecting the requirements of the DQA and EPA Order 5360.1;[37] (2) provisions for quality system implementation; (3) quality management plans for each organization unit; (4) quality assurance work plans for those units; (5) annual quality assurance reports to be reviewed and approved by designated senior agency officials; and (6) quality assurance project/plans. The Guidelines should extend these requirements to all information encompassed by the Act, including but not limited to those categories of information set forth in Sections 1.2 and 1.3 of the EPA Quality Manual. Moreover, the Guidelines should commit the Agency to periodic review, with the opportunity for public notice and comment, of this enhanced, more robust quality process.

Consistent with the above, GE also believes EPA should articulate, as part of its Guidelines, an "environmental information management system" to provide a means by which EPA will periodically evaluate its information quality policies and procedures to ensure that they are functioning in a manner consistent with DQA objectives and requirements. Such a system should embrace certain key principles, including: (1) the accountability of EPA staff and

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[37] The Manual is intended to implement program requirements for mandatory quality systems defined in EPA Order 5360.1, "Policy and Program Requirements for the Mandatory Agency-Wide Quality System."

contractors for developing information products that comply with the Agency's Guidelines; (2) comprehensive training in data quality requirements/compliance; (3) emphasis on application of quality requirements at the outset of information product development; (4) stakeholder involvement early and often in the process; (5) pursuing the most knowledgeable and reliable services reasonably available to confirm the objectivity and utility of information; (6) full consideration of the possible future use of the information; and (7) the enumeration of steps to follow.[38]

C. EPA Should Follow the Approach Taken by Other Agencies and List Specific Examples of Information Products That Are Representative of Identified Categories of "Influential Information."

EPA's approach to the designation of "influential" information must conform to the OMB definition. OMB defines information as influential if "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." OMB Guidelines, Section V.9. In this regard, EPA has indicated that it will follow OMB's final guidelines and apply higher standards of quality to "influential scientific, financial, or statistical information, " a position that GE endorses.

GE also recommends that in addition to the classes of information set forth in Section 3.2 of the draft Guidelines that the Agency indicates will generally be viewed as "influential," EPA identify and list specific examples of information products that are represented or encompassed by those categories. This approach has, in fact, been taken by other agencies in issuing their

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[38] Many of these considerations are addressed in OMB's Guidelines for its own information dissemination. *See* OMB Guidelines, Part I.A. noticed at 67 Fed. Reg. 21,779 (May 1, 2002).

draft guidelines. For example, in the guidelines proposed by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry ("CDC/ATSDR"), CDC and ATSDR have stated that they will consider "information disseminated in *MMWR [Morbidity and Mortality Weekly Report] Recommendations and Reports*, the Hazardous Substance Release/Health Effects Database, and *Federal Register* publications related to science as influential scientific information." *See* CDC/ATSDR draft Guidelines, Section VII.[39] Such an approach should facilitate a clearer understanding both by affected parties and EPA personnel of what information should be considered "influential" for purposes of review.

GE urges EPA to adopt a similar approach that identifies categorical types of information that should ordinarily be regarded as "influential." By way of example, information set forth in the Integrated Risk Information System "(IRIS") is used across EPA program offices and by state governments for regulatory standard setting and should be presumptively regarded as influential. Indeed, that information seemingly comports with the characteristics of at least two of the four classes of information set forth in the draft Guidelines as "influential" information. *See* Section 3.2. A "listing" of IRIS information as "influential" would be appropriate and beneficial, and would eliminate any uncertainty regarding the proper classification of this scientific information.

By providing additional "listed" categories of information that EPA considers "influential", the Agency can both provide certainty in individual cases and furnish examples for

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[39] 67 Fed. Reg. 21,685 (May 1, 2002), available at <http://www.hhs.infoquality/cdc.htm.>.. CDC/ATSDR have also apparently taken the position that the "influential" information they disseminate extends to information based on "analysis of the risks to the public of ... exposure to hazardous substances", with "risk" being defined as "the likelihood that injury or damage is or can be caused by a substance, technology, or activity." *See id.* A definition of "influential" that covers such information appears to fall squarely within OMB's definition of the term, and GE encourages EPA to adopt such a standard.

purpose of reference in close cases, thereby minimizing unnecessary administrative burdens on Agency resources in the determination of what represents such information. Accordingly, GE recommends that the Agency identify the following additional categories and types of information as "influential":[40]

(1) As noted above, chemical information contained in IRIS;

(2) chemical classifications (*e.g.*, EPA's list of chemicals that are persistent, toxic, and bioaccumulative; EPA's classification of chemicals as carcinogens; and any characterization of chemicals as actual or suspected endocrine disrupters);

(3) human health and ecological risk assessment guidelines;

(4) major risk assessments likely to have a clear and substantial impact on particular products or processes (*e.g.*, assessments of whether phthalates are endocrine modulators or whether dioxin causes cancer);

(5) site-specific risk assessments, remedial investigation, feasibility studies and remedy decision documents conducted under RCRA or CERCLA entailing cleanup costs equal to or greater than $25 million;

(6) models and similar "information products" designed to characterize the risks posed by particular facilities or products, or by ambient conditions at a particular location (*e.g.*, National Air Toxics Assessment, Risk Screening Environmental Indicators Model), as well as the results of use of these tools;

(7) tools that rank facilities, entities, organizations, regions, or localities by environmental performance or quality factors;

(8) information which is intended to, or can reasonably be expected to, influence public opinion;[41]

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[40] GE agrees that the four classes of information proposed by EPA as "influential" are properly classified as such. However, for reasons that should be evident, the first category should extend to "information disseminated in support of top Agency actions that demand the ongoing involvement of the Administrator's office or [not "and"] extensive cross-Agency involvement."

[41] As discussed above, EPA's categorical exclusion of "distribution of information in press releases and similar announcements" from coverage under the Guidelines is unwarranted. Such announcements often constitute the first (or early) dissemination by EPA of important determinations or findings it has made. They also can seek to influence public opinion by trying to persuade readers of the force behind the Agency's actions. Where press

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(9) information which is intended to inform Congress or respond to Congressional inquiries; and

(10) information obtained from other government sources, and relied upon and disseminated by EPA, that falls within any of the above-referenced categories.

D. The Guidelines Should Set Forth More Affirmative Measures to Ensure That Influential Information Obtained from States and Localities and Disseminated by EPA Meet the Quality Standards of that Act.

It is important for the Agency to describe in greater detail how the objectives of the Data Quality Act will be implemented in the context of its relationship to state and local regulators. As the Agency points out, these other governmental entities manage and implement federally authorized or supported programs, communicate with the public about issues of concern, and collect, use and disseminate a wide range of important information, much of which is relied on and disseminated in turn by EPA. They also look to EPA for direction, supervision and approval on many matters relating to environmental health and safety. EPA's draft Guidelines acknowledge that the Agency needs to "consult" with the network of federal, state, local, and tribal governments that supply and use information disseminated by EPA to ensure that the Guidelines are "appropriate and effective." Nonetheless, the Agency is completely silent with respect to how it intends to ensure that "effectiveness" with respect to the aspects of its mission that involve state and local governments.[42]

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releases seek, or can be reasonably expected to, influence public opinions on matters involving the use of science, they should also be considered "influential" for purposes of the Guidelines.

[42] Section 3.5 of the draft Guidelines, which is ostensibly intended to address the issue of ensuring and maximizing the quality of information from state governments and third parties, similarly leaves commenters in the dark. There, EPA states summarily that it is "taking . . . steps to ensure that the quality and transparency of data and information provided by external sources is sufficient for the intended use," but never gives any indication what those steps are and what comment from stakeholders would be helpful in fashioning that process.

In this regard, it is clear that the broader objectives of the Act can – and must – be achieved not only through the data quality measures EPA ultimately applies to information generated by itself, but through the identification and pursuit of all other reasonable measures and authorities available to EPA in the context of its supervisory/working relationship with the states to ensure the quality of data furnished by states (and local governments) and disseminated by EPA. The final Guidelines should therefore explain how the Agency will ensure their effectiveness with respect to information furnished to EPA by state and local governments, as well as by other parties who submit information which EPA disseminates.

At a minimum, EPA must apply the "quality" principles and the review mechanisms mandated by the Act to any influential information obtained by the Agency from states and local governments that it subsequently maintains, uses and disseminates. Additionally, EPA should take affirmative steps to communicate determinations that information products fail to meet quality standards established by the Act whenever the Agency makes such a determination, irrespective of whether the information product came from a state in the first instance. In the case of a deficient state information product, EPA should also determine whether, as a result of the Agency's data quality review, the state program that produced the non-conforming information product will in effect be acting in a manner inconsistent with the federal program, should it continue to use or disseminate that product. Under such circumstances, it will be appropriate for EPA to direct the state to cease the reliance and dissemination of the faulty information, although the Agency should take all reasonable measures at its disposal to dissuade state and local governments from using such information products in any event.

VI. EPA's Information Correction Mechanisms and Procedures do not Meet the OMB Requirement to Specify Appropriate Time Periods for Agency Decisions on Whether and How to Correct Information

As a general matter, the Act and the OMB Guidelines leave no doubt that EPA's DQA guidelines are intended to apply to all aspects of the Agency's operations. This intent extends to both pre-dissemination quality review procedures and administrative information correction mechanisms.[43]

With respect to information correction, the Agency's guidelines are to ensure effective administrative mechanisms "allowing *affected persons* to seek and obtain, where appropriate, *timely correction* of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines." OMB Guidelines, Section III.3. (emphasis added). Among other things, agencies "*shall* specify *appropriate time periods* for agency decisions on whether *and how* to correct the information, and agencies *shall* notify the *affected persons* of the corrections made." *Id.* at Section III.3.i. (emphasis added). Moreover, agencies "*shall* establish an administrative appeal process to review the agency's initial decision, and *specify appropriate time limits* in which to resolve such requests for reconsideration." *Id.* at Section III.3.ii. (emphasis added). That appeal process must be an "objective" one that "*will ensure* that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement." 67 Fed. Reg. 8458 (Feb. 22, 2002). Unfortunately, as discussed below, EPA's draft Guidelines fail to heed these OMB directives in most respects.

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[43] While it may be appropriate for the Agency to define discrete, narrow, and carefully-crafted exceptions to the pre-dissemination review and administrative correction processes, the Guidelines should establish a strong presumption in favor of the application of the Guidelines and carefully circumscribe the circumstances in which departure from them is warranted.

A. The Definition of Affected Persons Should be Expanded to Include Persons who Use Influential Information

The Act specifically mandates that EPA shall establish administrative mechanisms allowing "affected persons" to seek and obtain correction of information maintained and disseminated by the Agency that does not comply with the OMB Guidelines. DQA, Section 515(b)(2)(B). The EPA Guidelines appear to suggest that "affected persons" will be limited to those who are either *directly* benefited or injured as a result of the information in question. Such a definition, however, would be too limited, given EPA's strategic mission and the role it plays in providing information that the public and the regulated community uses in making personal or business decisions.

In this regard, OMB has made clear that the definition of "affected person" should be applied broadly so as to ensure full public access to the information correction process. The June 10, 2002 OMB Review, Section V ("Affected Person"). By way of explanation, OMB has stated that the focus of the correction process should be on the "merits of the complaint, not the possible interests or qualifications of the complainant." *Id.* To this end, OMB has indicated that the definition of "affected persons" shall be broad enough to include those "seeking to address information about themselves as well as persons who use information." In this regard, GE also notes that a sizable number of other federal entities have already defined the class of parties eligible to invoke their administrative correction mechanisms as specifically including all "those persons who use the information."[44]

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[44] For example, the U.S. Departments of Defense, Transportation, and Treasury proposed such a definition in their guidelines, as did agencies as diverse as the Internal Revenue Service and the Office of Science and Technology Policy ("OSTP"). Other agencies whose central missions, like that of ATSDR, involve protection of human health proposed even more expansive definitions. For example, the Food and Drug Administration defined "affected
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Such a definition would also appear to be appropriate with respect to the EPA Guidelines given that "influential" information (*e.g.*, overstated cancer risk in drinking water) may in fact have a substantial impact on private sector decisions even if it does not cause a direct or palpable injury *per se*. For example, such information may serve as an unwarranted deterrent to the private sector or the general public with respect to significant decisions and choices they make in their lives and businesses, or the confidence they have in the critical services and information that government provides.[45] Accordingly, GE recommends that EPA broaden the definition of "affected persons" so that it extends as well to "persons who use information."

B. EPA Should Post Requests for Information Correction, Administrative Appeals, and Agency Determinations Thereof

As noted above, the OMB guidelines direct that "affected persons" be notified of information corrections made. Of course, persons "affected" by corrected information – or by requests for the same – may extend well beyond those who actually request the correction in the first instance.

As such, GE strongly urges EPA to establish on its website a centralized electronic docket for (i) information correction requests that are submitted to the Agency, (ii) administrative appeals of denials of those requests; and (iii) Agency decisions to correct information. Such an approach would serve to: (1) enhance the administrative efficiency and regularity of the correction/appeal process, (2) provide an effective, efficient and timely vehicle

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person" as "any interested person," and the Consumer Product Safety Commission effectively defined the term as "any person."

[45] A number of judicial decisions have observed that accurate, informative data are important to and protect society and communal interests. For example, not only does the public have an interest in accurate information pertaining to such subjects as drinking water or ecological risks, but economic and business interests have legitimate interests in maintaining efficient, safe and scientifically advanced drinking water systems and protected habitats.

for apprising other potentially "affected persons" and the public of challenges to (and corrections of) information, (3) link affected parties to EPA resources that can provide information relevant to the review process and how other affected parties might participate, as appropriate, and (4) provide an internal tracking mechanism to ensure that the Agency approaches data correction in a consistent, transparent, effective, and timely manner.

Consistent with these objectives, practical and procedural considerations strongly suggest that any request for correction must proceed from a written complaint filed with a designated intake officer. This appears to be the approach suggested by EPA, and GE concurs in it and offers the following supporting comments:

(1) The complaint should be required to set forth:

- a detailed description of the specific information that needs to be corrected;
- the specific reasons for believing the information is in error and supporting documentation, if any; and
- the specific recommendations for correcting the information.

(2) The Website posting of the complaint should include:

- the written complaint and its assigned matter/docket number;
- the date the challenge was filed and docketed;
- the name of the requestor;
- a description of the challenged information (including a hypertext link if it is disseminated electronically on the EPA Website);
- a summary of the basis for the challenge and the actual complaint, as well as any supporting materials that reasonably may be capable of electronic reproduction in PDF format; and
- the name, e-mail address, and phone number of an EPA employee or contractor who may be contacted for further information regarding the complaint.

To ensure public access and notice for those who do not have access to the Internet, and for the purpose of making available those supporting materials which would not lend themselves to electronic posting, a single, centralized mirror "paper" docket should be maintained by the Agency that contains all such pending challenges across the agency.

A comparable system should be established for pending administrative appeals of correction request denials. (This system will presumably facilitate the development of the Agency's own annual report to OMB, required by the statute and OMB Guidelines.) In addition, the Agency should provide for appropriate website posting of correction request and administrative appeal decisions.

C. EPA Should Adopt Procedures for "Flagging" Uncorrected Data Requiring Correction

Depending upon the nature of the correction request and the underlying challenged information, the Agency may be able promptly to identify incorrect information that it is disseminating, but not be in a position to supply corrected information in a short time period. For example, as a result of arguments provided by a person challenging information resulting from the Agency's use of a model, EPA may determine that the model does not provide accurate or reliable information. While it may be readily apparent, based upon the correction request, that the data and conclusions drawn from the model are inaccurate, a complete analysis of the model's deficiencies and actual correction of the error(s) in the model (and information stemming from the model's use) necessarily may take an extended period of time.

It is reasonable to expect that this type of situation will be a frequent occurrence relative to a number of requests the Agency receives. In view of this dilemma, GE strongly urges that the administrative review and correction process be structured to make provision, under specified circumstances, for "flagging" of information and data disseminated by the Agency that it

determines is flawed but is not able to correct in a short period of time (*e.g.*, within 30 days). In that way, regulators and the public who may look to that information to inform their actions will have notice that it is in the process of being withdrawn or corrected. GE encourages EPA to post as well the estimated time frame within which the correction effort can be expected to be completed. *See* Section VI.G below. Notification of this type will alert all persons interested in the information to problems associated with reliance on it.

D. The Guidelines Must Establish Information Correction Request and Administrative Appeal Procedures

The draft Guidelines are also largely silent with respect to the procedures that will govern information correction requests and administrative appeals. At least for "influential" information, the Agency should incorporate common sense procedures to ensure efficient, effective, thoughtful, consistent, and timely reviews. These provisions should include, at a minimum:

- provision for record documentation (both at the pre-dissemination and initial review stages);
- certification of that record;
- written advocacy submissions; and
- written findings and conclusions.

Additional mechanisms for reviewing the quality of such information might include:

- hearings and arguments on the record at the option of the Agency appeals body;
- opportunities for alternative dispute resolution, such as mediation; and
- the use of technical experts to guide the deliberative process of the appeals body.

These additional mechanisms should be available only if suggested by any of the parties *and* agreed to by the appeals body.

E. Timeframes for Resolving Correction Requests and Appeals

As noted above, the OMB Guidelines require EPA to specify time limits for decisions on both initial information correction requests and administrative appeals from adverse determinations with respect to those requests. It is surprising, therefore, that the draft Guidelines fail to set any time frames for review and decision by the Agency in either case. The Agency must set presumptive time limits in the Guidelines by October 1, 2002.

As a general matter, GE believes that the following principles should govern the Agency's resolution of suitable timeframes for these purposes:

- It is appropriate to provide for shorter time frames, *i.e.*, 14 days or less, when review involves a correction that is ministerial rather than one that implicates complex information products or significant aspects thereof.
- In all cases, however, appeals should proceed within the 60-day time frame that is ordinarily applied in other administrative appeal venues within the Agency, with a provision for extending that time frame for good cause.
- The Agency should address not only deadlines for action by the reviewing official, both in the course of the initial review and the appeal therefrom, but also time frames for submissions by parties in the appeal process.
- Deadlines should be firm within the Agency[46] and provide for an immediate appeal to an appropriate senior agency authority for a directive to undertake review on an expedited basis, if the Agency reviewing official or appeals body fails to meet its reviewing deadline in the first instance.[47]

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[46] To provide some flexibility where truly warranted, the process could provide for (i) very limited extensions of time for submissions by the parties for good cause shown, and (ii) short extensions (*e.g.*, no more than two weeks) of the time available for Agency decision upon notice to the parties with an explanation for the delay. However, such extensions should only rarely occur if the objective of timely correction of flawed data is to be well served.

[47] Other agencies have proposed approaches that are much more responsive to DQA objectives and OMB Guideline directives than are the draft Guidelines. For example, CDC/ATSDR have indicated that they "will respond to all requests for correction within 45 working days of receipt. If the request requires more than 45 working days to resolve, the requestor will be informed that more time is required, notified of the reason why, and provided an estimated decision date." CDC/ATSDR draft Guidelines, Section VI.B.

F. The Appeal of the Initial Review Should be Conducted by Impartial Agency Officials With Strong Technical and/or Legal Credentials, Whose Positions Are Dedicated to Such Activities, Insulated from Program Policy Pressures, and Allowed Access to Adequate Resources to Effectively Evaluate Challenges

A relevant program office will be in the best position to conduct actual pre-dissemination information quality review and to provide context, resources and evaluation in connection with any initial challenge to information. However, in those instances in which such a challenge is not ministerial in nature, but rather interpretative or analytical, experience and common sense suggest that the objectivity, transparency and completeness of the review (and thereby, the assurance of the quality of the data) will benefit most from an administrative appeal process that functions at the administrative appeal and decisional level independently of the office that had responsibility for generating, maintaining or disseminating the information. Indeed, the OMB Guidelines recognize that reality and mandate this result.[48]

Nonetheless, the Agency has proposed that final administrative appeal decisions be rendered by the head of the EPA program office or region that originally had responsibility for the information dissemination and conducted the initial review. Such an approach implicates substantial issues regarding the objectivity of the review of the appeal (and public confidence in the same) but also raises serious questions with respect to consistency within the Agency.[49] In

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[48] OMB's Guidelines expressly require there must be an "objective process" ensuring that the "office that originally disseminates the information does not have responsibility for both the initial response and the resolution of the disagreement." 67 Fed. Reg. at 8458.

[49] It could be argued that the involvement of the program head in deciding the appeal is necessary to ensure that highly technical issues are decided by someone with expertise. That argument, however, is belied by the composition of both many administrative law judges and the state and federal judicial system, which rely on generalists with broad experience and wisdom, rather than specialists in an area of technical expertise. As with any court or administrative law judge, a sound decision on the merits of even a highly technical issue can be ensured
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order for an effective, institutional information quality program to emerge Agency-wide, decision making cannot be decentralized. With more than fifteen regions and offices acting of their own accord on issues that will affect the entire Agency, the potential for inconsistent, disjointed and inappropriate policies is likely to become rife. Instead, a centralized and impartial appeal process should clearly be established.

Other agencies have already taken this approach. For example, CDC/ATSDR's guidelines provide that the agency official who resolved the original complaint will not have responsibility for the administrative appeal. Instead, the office responsible for administering the information correction process will direct all appeals to an appropriate CDC official in the Office of the Director (or, in the case of ATSDR, the Administrator of ATSTDR) based on the nature of the information product and complaint. *See* <http://www.hhs.gov/infoquality/cdc.htm#VIC>.

Although there are a number of potentially viable options for achieving the objectives of a meaningful, timely, impartial, and centralized administrative appeals process,[50] GE believes that it would be advisable for EPA to create a standing, dedicated appeal body composed of

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through allowing the program office – as well as the outside petitioner – to present their arguments from their advocacy points of view.

[50] GE is aware that a number of parties have advocated centralizing appeals within EPA's Office of Environmental Information ("OEI"); EPA, on the other hand, has proposed that OEI manage the administrative information correction mechanisms. GE has no objection to OEI's management of the correction mechanisms, and believes that it would be very useful for OEI to have resulting notice of the complaints being made regarding the quality of information being disseminated by EPA. However, GE questions whether OEI is the optimal decisionmaker for these appeals. The option of having OEI decide appeals admittedly has the advantage of having those appeals heard by individuals presumably knowledgeable about – and concerned with adherence to – the Agency's current information quality policies and procedures. However, it suffers from the distinct disadvantage of having the office responsible for creating and managing those information quality systems decide challenges regarding whether those very systems have resulted in information that fails to comport with DQA quality standards. Given OEI's vested interest in defending the adequacy of the systems it has created, this approach seems problematic. One possible way to take advantage, nonetheless, of the expertise that OEI possesses with respect to information quality issues is to appoint individuals with requisite prior OEI experience to serve as one member of the independent three-member appeal panels GE recommends above.

appropriately qualified scientific, legal, and regulatory specialists to serve on three-member appeal panels. To ensure their independence from the missions of the program offices, the members of this body should be appointed by the Administrator and be situated within the Administrator's office. In addition, to facilitate the work of those panels, the Agency should provide the appeal body (i) authority to seek expert review and analysis in an open and transparent manner from entities such as the Science Advisory Board, and (ii) assistance from qualified staff members hired for and dedicated to that purpose.

In sum, the appeal of the initial review ideally should be conducted by impartial agency officials with strong technical and/or legal credentials, whose positions are dedicated to such activities, insulated from program policy pressures, and allowed access to adequate resources to effectively evaluate challenges. One possible model from the Agency's own historic organizational structure is creation of a new technically proficient, independent appeals board with a mission along the lines of that of the Office of Policy, Planning, and Evaluation, which (until effectively disbanded by Administrator Browner) served as a "watchdog" over the program offices with respect to cost-benefit and other policy considerations. In this case, the mission of the appeals board would be to safeguard compliance with the OMB and EPA Guidelines by Agency program offices.

No matter what the model employed, however, the Agency needs to ensure that the appeals body possesses the requisite expertise, resources and independence (both actual and perceived) to handle what could well be numerous and varied appeals in a manner that will enjoy the confidence of the public and private sectors. June 10, 2002 OMB Review, Section V ("Objective Appeals Mechanism"). As OMB has emphasized, it is critical to the objective of the

Act that EPA fashion a complaint an appeal process that will "build confidence in *both the reality and appearance* of a neutral, fair decision mechanism."

VII. The Guidelines Should Foreclose the Use of Defective Information Products and Set Firm Deadlines for Timely Review

The draft Guidelines also fail to address two related, fundamental issues posed by implementation and maintenance of information products that are inconsistent with the quality standards required by Data Quality Act: timely correction of information determined by the Agency to be flawed and prohibitions on further use and dissemination of such information until it is corrected. Given the central importance of these issues, GE offers below specific recommendations as to how they should be resolved.

A. EPA Should Foreclose Any Further Use of Flawed Information Products

It would defeat the purpose and objectives of the Data Quality Act if EPA was able to use and disseminate information determined not to conform to the Act, the OMB Guidelines and/or the EPA Guidelines unless and until that information was corrected. Accordingly, the Guidelines should make clear that further use and dissemination of that information by EPA – and by those parties operating under a contract, cooperative agreement, or other such arrangement with the Agency – should be prohibited until the information is corrected.

To address this point, GE strongly urges EPA to adopt the approach taken by the U.S. Department of the Interior ("DOI") in its draft DQA Guidelines. Under those guidelines, if an initial information correction request is determined to be meritorious, the relevant DOI bureau or office "*shall* take reasonable steps to withdraw the information from the public domain and from any decision making process in which it is being used . . . . [t]he bureau or office may determine

the schedule and procedure for correcting challenged information, but *may not* disseminate the challenged information *in any form* until it has been corrected.[51]

Similarly, if a successful appeal is taken of a denial of an initial challenge to information or of a proposed correction to information, "[t]he challenged information *will be* withdrawn, to the extent practicable, from the public domain and *will not* be used in any [DOI], bureau, or office decision making process until is corrected."[52] As such, the DOI approach appears to establish an absolute prohibition on *any future* use or dissemination of successfully challenged information by DOI in any manner, and requires, through "reasonable steps" and to "the extent practicable," the "withdrawal" of information disseminated by DOI after October 1, 2002, but initially used by DOI before that date (*e.g.*, in a rulemaking).

GE believes that approach strikes an appropriate balance between the objectives of the DQA and the flexibility needed by federal agencies in determining how to address flawed information initially used in pre-October 1, 2002 actions, but newly disseminated and successfully challenged after that date. Accordingly, GE strongly urges the Agency to adopt a comparable approach and to state that the intent of the approach is as indicated in the last sentence of the previous paragraph.

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[51] "Information Quality Guidelines Pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001," U.S. Department of the Interior, Office of the Secretary, at Section III (emphasis supplied), *available at*< http://www.mms.gov/whatsnew>.

[52] *Id.* (emphasis added).

B. EPA Must Adopt Firm and Reasonable Timeframes for Correction of Defective Information Products

The Data Quality Act "requires" EPA to establish administrative mechanisms that, without exception, allow affected persons to "obtain" correction of information "that does not comply with the [OMB] guidelines." DQA, Section 515(b)(2)(B). In turn, the OMB Guidelines direct EPA to establish mechanisms that allow affected persons to "obtain . . . *timely* correction" of information that does not comply with the OMB or Agency guidelines. OMB Guidelines, Section III.3. (emphasis added). Despite these mandates, the draft Guidelines inexplicably fail to honor the uniform statutory right to correction, and do not even address the issue of the timing of correction of information once EPA has determined that correction is warranted.[53] In order to adhere to the aforementioned directives and to ensure, with respect to the timing issue, that "justice delayed" does not become "justice denied," EPA should address these issues in the final Guidelines.

The draft Guidelines state that "EPA may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources." Section 5.5, lines 761-762. Because the DQA admits of no exceptions to the right of information correction through an administrative mechanism, the Agency's attempt to insulate some undefined set of information from that right on the basis of administrative convenience is

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[53] Indeed, the draft Guidelines do not even require the Agency, upon a determination at either level of review that correction is warranted, to state – even generally – *what* corrective action will be taken. This deficiency should also be rectified. *See, e.g.*, CDC/ATSDR draft Guidelines, Section VI.B. (if a correction is warranted, CDC/ATSDR "will respond to the requestor by letter or e-mail, explaining the findings of the review and the actions that the agency will take . . . .").

inconsistent with the DQA. Accordingly, the quoted sentence should be deleted from the Guidelines.

GE recognizes that "one size can not fit all" with respect to the timing of correction of information that may differ dramatically in its significance and the difficulty of correction. That said, the Agency could nevertheless adopt certain principles that would presumptively govern the time frame for correcting information:

- Correction of ministerial information should generally be accomplished within a short period, *e.g.*, no more than 14 days;

- With respect to other information, the office responsible for dissemination and correction of the information should be required to provide, either upon a favorable information correction request decision or to the appeals body upon its decision ordering correction, an estimate of the time required to correct the information and the reasons for that estimate. If the original affected party disputes the reasonableness of the time estimate provided, or if the EPA office fails to meet the estimated correction date, the appeals body should be authorized to (i) entertain challenges to the timeliness of the corrective action, and (ii) issue orders establishing time frames for correction.

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GE welcomes the Congressional mandate to maximize and ensure data quality and commends EPA for recognizing in its mission statement the importance of working closely with the regulated community and other stakeholders to accomplish those Congressional objectives. Consistent with that message, GE looks forward to opportunities to work with the Agency, as appropriate, to provide additional input and views on the draft Guidelines.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FOR IMMEDIATE RELEASE 2002-33
June 11, 2002

OIRA Administrator Calls New Guidelines a "Good Start"; Higher Quality Information Expected

Washington, D.C. -- In a memo to the President's Management Council released today, the OMB Office of Information and Regulatory Affairs (OIRA) praised federal agencies for issuing new guidelines that will improve the quality of information provided to the American people. A copy of the memo, which includes a detailed evaluation of the agencies' draft guidelines, follows this release.

"Receiving trustworthy information from the government is vital to the well-being of American communities and families. I am pleased to report that agencies have made a good start at improving the quality of this information for all Americans," said OIRA Administrator John D. Graham.

Graham commented that "the power of government information is enormous. A single statistic on a government Web site can cause a consumer to change his or her diet, a producer to stop using a specific input, an employee to refrain from making an equal-opportunity claim, and a mayor's office to allocate scarce funds to one health program rather than another."

In its detailed evaluation, OIRA proposes constructive strategies for improving the agencies' draft guidelines. The evaluation also highlights the quality of the agencies' administrative mechanisms for addressing public complaints.

The size and scope of the information released by the federal government is vast, as is its effect on the lives of many Americans. Leveraging the power of the Internet, the government regularly provides citizens with population figures, cost-benefit analysis reports, and economic indicators. Every statistic that government releases could be improved through the implementation of better data quality guidance.

The draft guidelines come as part of a year-long effort that began on September 28, 2001, when OMB issued government-wide information quality guidelines. Federal agencies were then required to draft their own guidelines tailored to the types of information they typically release.

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The final version of these agency guidelines, which require OMB review, will be available on the Internet by October 1, 2002.

The information quality law, which gives OMB the ability to request improved information guidelines from federal agencies, was passed by Congress due to concerns that information disseminated by agencies through Web sites, rulemaking notices and other means are not always of high quality. Scientific, statistical and financial information have been highlighted for improvement, especially if the data play an influential role in major public policy decisions.

BACKGROUND:

- The President's Management Council (PMC) is comprised of the Chief Operating Officer from each federal department and chaired by the Deputy Director for Management at the Office of Management and Budget (OMB).

- The Information Quality Law was passed by Congress in 2000 and signed into law by President Clinton.

- Rep. Jo Ann Emerson (R-Mo.) was the principal sponsor of the Information Quality Law.

-- memo follows --

June 10, 2002

MEMORANDUM FOR PRESIDENT'S MANAGEMENT COUNCIL

FROM: John D. Graham

SUBJECT: Agency Draft Information Quality Guidelines

The quality of information disseminated to the public by the Federal Government needs to be improved.

Reflecting this need, Congress recently directed OMB to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." The Administration is committed to vigorous implementation of this information quality law.

OMB issued government-wide information quality guidelines on September 28 last year. Each Federal agency is now required to issue its own guidelines that will ensure the quality of information that it disseminates. These guidelines must include mechanisms to allow the public to seek correction of disseminated information that does not comply with the information quality standards in the OMB or agency guidelines. To permit public participation and comment, and to facilitate interagency coordination, agencies are expected to make their draft guidelines available for public comment.

My staff and I have completed a preliminary review of the draft agency guidelines currently available for public comment. We want to thank you for the substantial effort and careful deliberation reflected in the agency drafts. Agencies, with highly diverse program responsibilities, disseminate a wide variety of kinds of information to serve many different purposes. The agency drafts properly reflect this variety.

Some agencies have developed particularly noteworthy provisions that I would suggest for consideration by other agencies in reviewing and revising their own draft guidance. I would also like to point out some provisions in agency drafts that do not appear consistent with the text and intent of the OMB guidelines or are otherwise contrary to Administration policy.

Based on our review, I have attached a discussion of important issues, identified noteworthy approaches for consideration, and provided guidance on those provisions that need to be adopted uniformly in all agency guidance. I request that you send this attachment to the appropriate officials who are responsible for developing your agency's information quality guidelines.

We have asked agencies to submit draft final guidelines to us for review by August 1 (which we have extended from an original July 1 deadline). We encourage you to use this extra

time to extend your public comment period. In light of the recent decision to allow additional time for agencies to extend the period for public comment on agency guidelines (and thus compress the time available for final OMB review), it is my intention to have these OIRA comments considered in conjunction with public comments as agencies shape their final guidelines.

As a related matter, I should note that Mark Forman of OMB is leading work on a content model for presenting information on the web. It will include guidelines on how to present web content, how agencies should identify web-based material, and general guidelines for what should go on the public internet.

Attachment

June 10, 2002

OIRA REVIEW OF
INFORMATION QUALITY GUIDELINES DRAFTED BY AGENCIES

By October 1, 2002, agencies must publish in the *Federal Register* a notice that the agency's final guidelines are available on the Internet. Agencies must also provide OMB an opportunity to review each agency's draft final guidelines before they are issued. Drafts must be submitted to OMB no later than August 1.

The underlying legislation is Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658). The OMB Information Quality Guidelines can be found in the *Federal Register* for September 28, 2001 (66 FR 49718), and, as amended, for February 22, 2002 (67 FR 8452).

This attachment discusses important policy issues raised by the agency drafts, identifies noteworthy approaches for consideration, and provides guidance on those provisions that need to be uniformly adopted in all agency information quality guidelines. We urge that draft guidelines submitted for OMB review reflect consideration of this guidance as well as the public comments.

I. SCOPE OF AGENCY GUIDELINES.

In this topic, we discuss a number of constructive approaches agencies used to define the kinds of information that are covered by their guidelines. In some cases, we refer to provisions from agency drafts. These examples are quoted at the end of this attachment.

We cite these agency draft provisions as useful constructive approaches. We caution, however, that these examples are only agency proposals. Based on public comment and other review, the agencies may further refine these examples.

The OMB definitions of "information" and "dissemination" establish the scope of these guidelines. Both definitions contain exceptions. Agencies have elaborated upon the definitions of information and dissemination, and the exceptions thereto, to both broaden and narrow their scope. The specific examples discussed below include modifications that appear reasonable and consistent with the approach OMB takes in its guidelines, as well as suggestions for improvement and greater consistency with the OMB guidelines. We suggest that agencies consider these approaches for their own use.

Use of Statements of "Intent" to Define Scope. Some agencies used statements of intent or purpose to limit the scope of these guidelines. Such use of "intent" clarifies the nature of the inclusion or exclusion in a way to avoid having incidental or inadvertent public disclosure undermine the practical administration of the definition or exclusion. For example, some agencies insert the concept of "intent" into the exemption for intra- or inter-agency use of sharing

of information, e.g., exempted is "information ... not disseminated to the public, including documents intended only for inter-agency and intra-agency communications" (ED, 1 & 4). On the other hand, some agencies quote this definition as stated in the OMB guidelines literally, and do not insert a concept of intent. They may wish to include a concept of "intent" to avoid inadvertent public disclosure from undermining practical administration of the guidelines.

Exemption for Press Releases. Some agencies narrowed the exemption in the OMB definition to provide that the agency should already have disseminated the information discussed in the press release in another way. For example, EPA states "These guidelines do not apply to press releases, fact sheets, press conferences or similar communications in any medium that announce, support the announcement or give public notice of information EPA has disseminated elsewhere" (EPA, 15). This limitation avoids creating an incentive to misuse press releases to circumvent information quality standards.

Exemption for Public Filings. Some agencies refined the exemption for public filings to permit agencies to "pass through" information not subject to the guidelines while properly applying the agency and OMB guidelines to third-party information that the agency disseminates. Agencies need to qualify the public filing exemption to ensure that the agency guidelines continue to apply to third-party information that the agency disseminates, as we discuss below under II, "Coverage of 'Third-Party' Information under the Guidelines."

Exclusion For Agency Employed Scientist, Grantee, or Contractor. The preamble to the OMB guidelines discusses situations in which the dissemination of information by an agency-employed scientist, grantee, or contractor is not subject to the guidelines, namely those situations in which they "publish and communicate their research findings in the same manner as their academic colleagues" and thus do not imply official agency endorsement of their views or findings (67 FR 8453-54, February 22, 2002). On the other hand, an agency disseminates information "where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release" (67 FR 8454, February 22, 2002). Agencies that did not explicitly include such an exemption may wish to consider doing so, but need to do so in the carefully balanced ways quoted at the end of this attachment.

Exclusion for Testimony and Other Submissions to Congress. Some agencies exclude "information presented to Congress (as part of the legislative or oversight processes, e.g., testimony of officials, information or drafting assistance provided to Congress in connection with pending or proposed legislation) *that is not simultaneously disseminated to the public*" (Justice, 3; DOT, 9). As with the exemption for press releases, we think it would be better for agencies to narrow this exemption to provide that the agency should already have disseminated the information discussed in the testimony in another way. This limitation would avoid creating an incentive to misuse testimony and other submissions to Congress to circumvent information quality standards.

Exemption for Subpoenas or Adjudicative Processes. The preamble to the OMB guidelines states that "The exemption from the definition of 'dissemination' for 'adjudicative processes' is intended to exclude ... the findings and determinations that an agency makes in the course of

adjudications involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal" (67 FR 8454, February 22, 2002). Some agencies adapted the OMB exception very carefully. Other agencies may have broadened this exemption beyond OMB's intent; they need to limit this exemption carefully to be consistent with OMB's intent both as to the adjudicative procedures that are included and the scope of the information covered.

Effective Date. The OMB guidelines establish two somewhat different effective dates (III.4). An agency's obligation to conduct a pre-dissemination review of information quality starts only on October 1: "The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002." An agency's obligation to allow the public to seek the correction of information that does not comply with the information quality standards in OMB or agency guidelines starts on October 1, 2002, for information that the agency disseminates on or after October 1, 2002, even if the agency first disseminated that information before October 1: "The agency's administrative mechanisms, under paragraph III.3, shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information."

Some agencies followed the OMB guidelines carefully in describing when the information quality guidelines will take effect: "The DOJ information quality guidelines will become effective on October 1, 2002. These guidelines will cover information disseminated on or after October 1, 2002, regardless of when the information was first disseminated" (Justice, 2). Other agencies need to be careful to track accurately the OMB guidelines in this regard (III.4).

The effective date for the agency's administrative mechanisms raises the issue of what constitutes agency dissemination of information after October 1, 2002, if the agency first disseminated this information earlier.

DOT defines dissemination after October 1 to exclude archived information that had been disseminated previously. "As provided in OMB's guidelines, these guidelines apply only to information disseminated on or after October 1, 2002. The fact that an information product that was disseminated by DOT before this date is still maintained by the Department (e.g., in DOT's files, in publications that DOT continues to distribute on a website) does not make the information subject to these guidelines or to the request for correction process" (DOT, 23). This interpretation is consistent with OMB's intent, and equivalent to the "archival records" exemption.

Still to be considered is how a complainant demonstrates that an agency disseminates information after October 1, 2002, if the agency first disseminated that information before October 1, 2002. For example, existing official agency data bases, publicly available through agency websites or other means, that serve agency program responsibilities and/or are relied upon by the public as official government data, need to be subject to the Section 515 administrative

mechanisms to address public complaints because they are, in effect, constantly being redisseminated.

II. COVERAGE OF "THIRD-PARTY" INFORMATION UNDER THE GUIDELINES.

The preamble to the OMB guidelines states, "If an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines" (67 FR 8454, February 22, 2002). Reinforcing this statement of policy, OMB also provided an example in its preamble concerning the applicability of the OMB and agency information quality standards to third-party studies relied upon by an agency as support for a proposed rulemaking, even if the third-party studies had been published before the agency's use of them (67 FR 8457, February 22, 2002).

DOT incorporated these principles from the OMB guidelines by stating that an agency disseminates information if it relies on information in support of a rulemaking. "If the Department is to rely on technical, scientific, or economic information submitted by, for example, a commenter to a proposed rule, that information would need to meet appropriate standards of objectivity and utility" (DOT, 3). "The standards of these guidelines apply not only to information that DOT generates, but also to information that other parties provide to DOT, if the other parties seek to have the Department rely upon or disseminate this information or the Department decides to do so" (DOT, 8).

EPA explicitly includes a provision embodying the OMB example: "If a particular distribution of information is not covered by these guidelines, the guidelines may still apply to a subsequent distribution of the information in which EPA adopts, endorses or uses the information to formulate or support a regulation, guidance, or other Agency decision or position" (EPA, 17). Other agencies – particularly those likely to be involved with using and/or disseminating "influential" information – must include similar provisions in their guidelines.

III. AGENCY COMMITMENT TO INFORMATION QUALITY STANDARDS.

In this topic, we discuss (1) ways in which agencies need to commit to information quality standards, and (2) aspects of how those standards should be defined.

Performance Standards. The OMB guidelines state that, "Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) *as a performance goal* and should take appropriate steps to incorporate *information quality criteria* into agency information dissemination practices" (III.1). The "information quality criteria" are set forth in the definitions of "Quality," "Utility," "Objectivity," and "Integrity" (V.1-4). Closely related definitions are those for "influential" information, when used in the phrase "influential scientific, financial, or statistical information," and for "reproducibility" (V.9-10).

Each agency, in structuring its information quality guidelines, must state the agency's information quality criteria (as defined in the OMB and agency guidelines) as performance goals that the agency seeks to attain. Each agency needs to adopt explicitly each aspect of each definition of quality, utility, objectivity, and integrity as an agency information quality standard. Each agency also must explicitly state that it intends to achieve each standard. Otherwise, there will be no benchmark against which a public complainant will be able to suggest non-attainment.

The OMB guidelines also state that, "As a matter of good and effective agency information resources management, agencies shall develop a *process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated*" (III.2). Given that guideline, many agencies describe in considerable detail the kinds of activities they now undertake to assure information quality. Regardless, we stress that a mere description of current practices – however good – is not a substitute for explicit performance goals. At a minimum, each agency must embrace the OMB quality definitions as information quality standards they are seeking to attain. Examples of constructive agency statements are quoted at the end of this attachment.

In addition, some agencies and agency components do not appear to have adopted any standards for information quality (utility, objectivity, integrity) and/or defined "influential" or "reproducibility" in ways applicable to them. Each agency must either define its standards in ways applicable to it and consistent with the standards in the OMB guidelines, or explicitly adopt the standards from the OMB guidelines as the agency or component standards. For an agency that does not anticipate disseminating much information that is defined as "influential", we suggest that the agency simply adopt the standards from the OMB guidelines as its own.

Core Definition of "Objectivity". The OMB definition of "objectivity" is the most detailed and complex. This definition has different aspects, some that apply to all information covered by the OMB guidelines, others that apply only to "influential" information.

The first issue relates to all covered information. According to the OMB guidelines, " 'Objectivity' has two distinct elements, presentation and substance.

> a. 'Objectivity' includes whether disseminated information is being presented in *an accurate, clear, complete and unbiased manner* [-- as well as "within a proper context"].
> ...
> b. In addition, 'objectivity' involves a focus on ensuring *accurate, reliable, and unbiased* information" (V.3.).

Some agencies have summarized this aspect of the definition of "objectivity" accurately. Other agencies, in summarizing the OMB standard, appear to have left out some of the important standards; those agencies need to summarize the OMB standard accurately.

Peer Review. The discussion of peer review in the definition of "objectivity" relates to all covered information. "If data and analytic results have been subject to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity

[if the peer review satisfies 'the general criteria for competent and credible peer review' cited in the definition]. However, *this presumption is rebuttable* based on a persuasive showing by the petitioner in a particular instance" (V.3.b.i).

If an agency or component engages in peer review, it needs to discuss the ways in which it will adhere to the OMB standard in its guidelines. These peer review standards are not limited to information defined as "influential". These OMB peer review standards apply to all information covered by these guidelines, and need to be integrated into existing agency peer review standards applicable to covered information. In addition, agencies must point out – to be consistent with the OMB standard – that the presumption of objectivity afforded to formal, independent, external peer review is rebuttable, although the burden of proof, as explained more fully below, is on the complainant.

"Influential" and "Reproducibility". The next issue relates to agency treatment of influential information. "If an agency is responsible for disseminating *influential* scientific, financial, or statistical information, agency guidelines shall include a high degree of *transparency* about data and methods to facilitate the *reproducibility* of such information by qualified third parties" (V.3.b.ii; *see* V.9 for definition of "influential").

Several agencies provided a carefully considered discussion of the meaning of "influential" in their drafts. See provisions quoted at the end of this attachment.

"Original and supporting data" and "analytic results". With regard to influential information, the OMB guidelines further distinguish between "original and supporting data" and "analytic results".

> With regard to *original and supporting data* related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement (V.3.b.ii.A).
>
> With regard to *analytic results* related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. ...
>
> *i*. ... Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.
>
> *ii*.In situations where public access ... will not occur ..., agencies shall apply *especially rigorous robustness checks* to analytic results and document what checks were undertaken. Agency guidelines shall, in all cases, require a *disclosure of the specific data sources ... used and the specific quantitative methods and assumptions ... employed* (V.3.b.ii.B).

In draft agency guidelines, it does not appear that any agency undertook to delineate when

"original and supporting data" would be subject to a reproducibility requirement. Presumably, the public comment period is being used to seek views from the relevant scientific and technical communities. If, at the end of the public comment period, an agency is not prepared to identify what kinds of original and supporting data will be subject to the reproducibility standard, then the agency must include in its guidelines a statement to the effect that the agency shall assure reproducibility for those kinds of original and supporting data according to "*commonly accepted scientific, financial, or statistical standards*" (suggested language).

As to "*analytic results*," it appears that a number of agencies anticipate that reproducibility will sometimes not be achievable through public access because of confidentiality protections or other compelling interests. In such cases, some agencies do not mention the need to "apply especially rigorous robustness checks." Instead, they describe their intent to disclose specific data sources and specific quantitative methods and assumptions.
In such situations, agencies need to state explicitly their commitment to the standards stated in the OMB guidelines to applying "especially rigorous robustness checks" to analytic results *and document what checks were undertaken*. In addition, agency guidelines must, in all cases, explicitly require a disclosure of the specific data sources, quantitative methods, and assumptions used. We also recommend that agencies, in generating (or contracting to generate) influential information for dissemination, encourage arrangements that will permit appropriate public access to the related original and supporting data and analytic results.

Analysis of Risks to Human Health, Safety and the Environment. With regard to influential information, the OMB guidelines also state that, "With regard to analysis of risks to human health, safety and the environment ..., agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B))" (V.3.b.ii.C).
Some agencies discussed these Congressional risk information quality standards; some agencies discussed these in a limited context; and other agencies failed to mention these standards at all. Those agencies that are likely to use and/or disseminate influential information in their analysis of "risks to human health, safety, and the environment" need to clearly state that they are adopting the SDWA standards, or justify in what ways and for what kinds of information the agency is adapting the SDWA standards. FDA adapts the SDWA standards in a carefully considered, practical way (HHS/FDA, 18-20). We note that FDA read the SDWA standards as applicable to a risk assessment document made available to the public and did not limit their applicability only to documents related to a rulemaking; that is the proper approach.

IV. QUALITY INTEGRAL TO CREATION AND COLLECTION OF INFORMATION.

The OMB guidelines state that "As a matter of good and effective agency information resources management, agencies shall treat information quality as integral to every step of an agency's development of information, including *creation, collection, maintenance,* and dissemination. This process shall enable the agency *to substantiate* the quality of the information it has disseminated through documentation or other means appropriate to the information" (III.2).
Consistent with the OMB guidelines, the Small Business Administration explicitly included

"information development", "information acquisition", and "information maintenance" within the scope of its information quality guidelines, as quoted at the end of this attachment.

In this light, we note that each agency is already required to demonstrate the "practical utility" of a proposed collection of information in its PRA submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. Thus, we think it important that each agency should declare in its guidelines that it will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards. It is important that we make use of the PRA clearance process to help improve the quality of information that agencies collect and disseminate. Thus, OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines.

V. ADMINISTRATIVE MECHANISM TO ADDRESS PUBLIC COMPLAINTS.

Applicable Standards. The OMB guidelines state, "To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines" (III.3).

Some agencies discuss compliance with both the OMB and agency information quality standards in their discussion of the complaint mechanism. Others discuss compliance only with the agency information quality standards. To be consistent with the OMB guidelines, each agency should explicitly refer complainants to all of the applicable guidelines – the OMB, department, and departmental component's guidelines – as the applicable information quality standards.

"Affected Person". Some agencies defined "affected person" quite broadly. For example, "The term 'affected person' means anyone who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information" (OFHEO, 5). HHS took an even more open approach. Rather than defining "affected person," HHS just asks the complainant to *"describe how the person submitting the complaint is affected by the information error*" (HHS, 13). This invites the complainant to describe how he/she is affected, but specifically avoids any provision that would use this answer to limit or restrict who can point out an error in an agency's dissemination of information.

We prefer the HHS approach because it best ensures full public access to the complaint process, a goal of Section 515 and the OMB guidelines. The focus of the complaint process should be on the merits of the complaint, not on the possible interests or qualifications of the complainant. Other agencies need to adopt a similar approach.

Decision Criteria and Burden of Proof for Resolving Complaints. Several agencies state that:

"Requesters should be aware that they bear the 'burden of proof' with respect to the necessity for correction as well as with respect to the type of correction they seek" (Justice, 6). Having the burden of proof on the complainant is consistent with the OMB guidelines and will be helpful in permitting agencies to dismiss frivolous or speculative complaints. All agencies should make this clear in describing their complaint mechanism to the public. We quote at the end of this attachment carefully presented statements of the decision criteria and approaches that several agencies plan to follow in resolving complaints.

Time Periods for Resolving Complaints and Any Appeals. The OMB guidelines state, "Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made ... The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve ... requests for reconsideration" (III.3.i & ii).

Each agency must state in its guidelines the time periods for making decisions on both complaints and also on any appeals. Exceptions for unusual cases are appropriate.

Some agencies set a time limit within which, after receiving notice of an initial decision, the complainant could file an appeal, generally 30 days. Setting a time limit for filing appeals appears reasonable.

Some agencies also seek to set time limits for submission of original complaints (in effect, a form of a statute of limitations). OMB has concerns about the potential unintended effects of such limits and will be reviewing them carefully. Sometimes agencies continue, long after the agencies' initial dissemination, to adopt, endorse, or use information, and thus, in effect, continue to disseminate it. Similarly, agencies may continue to maintain ongoing official agency data bases, publicly available through agency websites or other means, that serve agency program responsibilities and/or are relied upon by the public, that are, in effect, constantly being redisseminated. The damaging effects of poor quality information may not occur or be perceived to have occurred until well after the information was originally disseminated.

An Objective Appeals Mechanism. The preamble to the OMB guidelines discusses our intent that agencies establish an objective appeals mechanism. "Recognizing that many agencies already have a process in place to respond to public concerns, it is not necessarily OMB's intent to require these agencies to establish a new or different process. Rather, our intent is to ensure that agency guidelines specify an objective administrative appeal process that, upon further complaint by the affected person, reviews an agency's decision to disagree with the correction request. An objective process will ensure that the office that originally disseminates the information does not have a responsibility for both the initial response and resolution of a disagreement" (67 FR 8458, February 22, 2002).

Some agencies discuss how they plan institutionally to structure their complaint and appeal procedures. Others do not. We strongly suggest that agencies describe to the public how they plan to resolve any complaints and appeals in order to build public confidence in both the reality

and appearance of a neutral, fair decision mechanism.

To enhance transparency, we also suggest that agencies provide the public with timely notice of what information the agency intends to correct after it makes a decision to correct it. In the annual report to OMB, agencies should also this information as well as a status report on the numbers and kinds of petitions for corrections, appeals, and any denials or grants of petitions for reconsideration or appeals. Agencies are encouraged, to the extent they practicably can, to give more timely disclosure of this information through, e.g., the use of electronic dockets or agency websites, they are encouraged to do so.

We note, in this regard, that a number of agencies emphasize that their guidelines are not intended to provide any right to judicial review. A few agencies even stress that their guidelines may not be applicable based on unspecified circumstances and that the agency may be free to differ from the guidelines where the agency considers such action appropriate.

Regardless of what kinds of litigation-oriented disclaimers the agencies may include, agency guidelines should not suggest that agencies are free to disregard their own guidelines. Therefore, if you believe it is important to make statements that your agency's guidelines are not intended to provide rights of judicial review, we ask that you not include extraneous assertions that appear to suggest that the OMB and agency information quality standards are not statements of government-wide policy, i.e., government-wide quality standards which an agency is free to ignore based on unspecified circumstances. In addition, agencies should be aware that their statements regarding judicial enforceability might not be controlling in the event of litigation.

VI. MELDING THE STATUTORY REQUIREMENTS OF SECTION 515 INTO THE PROCEDURAL REQUIREMENTS OF OTHER STATUTES.

The agencies take a uniform approach to complaints filed concerning information disseminated in the course of conducting a rulemaking under the Administrative Procedure Act (providing public notice to obtain public comment, then issuing the regulation in final form). The agencies meld the requirement to establish a Section 515 administrative mechanism to address public complaints into the procedures of the APA, NEPA, and other more specific public-comment statutes. This melding of Section 515 complaint procedures into the structure of existing statutes seems reasonable, and is discussed extremely well by a number of agencies. Of course, the substantive standards of quality, the information quality standards provided in the OMB and agency guidelines, remain applicable to any such dissemination of information. Examples of well-reasoned agency statements are quoted at the end of this attachment.

One of the agency discussions raises an interesting issue:

> Requests for Correction Concerning Information on Which DOJ Has Sought Public Comment. Information on which DOJ has sought public comment includes a notice of proposed rulemaking (NPRM), studies cited in an NPRM, a regulatory evaluation or cost-benefit analysis pertaining to an NPRM, a preliminary environmental impact analysis, a notice of availability, and request for comment on a risk assessment.

> DOJ's response to the request for correction will normally be incorporated in the next document it issues in the matter concerning which it had sought comment. The response will be provided in this document rather than in a separate communication. *DOJ may choose to provide an earlier response, if doing so is appropriate, and will not delay the issuance of the final action in the matter* (Justice, 6).

We suggest that Justice (and other agencies) explain in a little more detail the circumstances under which "an earlier response" might be "appropriate". We are sensitive to the procedures and long history behind the Administrative Procedure Act. However, we would suggest that agencies consider adding as criteria for making an early response a demonstration by a complainant of actual harm from the agency's dissemination of a study relied upon in a Notice of Proposed Rulemaking, or a demonstration by the complainant of substantial uncertainty as to whether the proposed rule will take an unusual length of time to go final.

Another interesting issue arises when an agency disseminates a particular study in a Notice of Proposed Rulemaking (NPRM), i.e., in the context of a particular agency policy decision, and a possible complainant has an interest in the study but not necessarily in the substantive policies embodied in the rulemaking. The possible complainant may only learn that the agency has disseminated the study by reading the NPRM, possibly after the comment period has expired. Agencies need to consider how those not directly interested in the rulemaking need to submit and receive consideration of a complaint about the study.

As a general matter, we urge each agency to carefully articulate the ways in which the APA, NEPA, and other more specific public-comment statutes meld with and thus have the apparent effect of superseding the administrative mechanisms to address public complaints provided by Section 515. For example, an agency may disseminate a risk assessment prior to publication of an NPRM. While the agency may anticipate that this risk assessment may be used in support of the NPRM, the agency should still permit complainants to file complaints under Section 515 unless the publication of the NPRM is imminent. Such a risk assessment may have impacts beyond the scope of the rulemaking.

COMMENTS OF THE GENERAL ELECTRIC COMPANY ON THE OFFICE OF MANAGEMENT AND BUDGET'S GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY FEDERAL AGENCIES

October 26, 2001

INTRODUCTION

The General Electric Company ("GE") appreciates the opportunity to comment on the Office of Management and Budget's ("OMB") Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies ("Guidelines"). 66 FR 49718 (Sept. 28, 2001). The Guidelines are intended to implement Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001 (the "Act"). GE understands that OMB is specifically requesting comment at this time only on the "capable of being substantially reproduced" standard referenced in Paragraphs V.3.B., V.9., and V.10 of the Guidelines. However, consistent with OMB's statements that it expects "continued refinement" of the Guidelines (66 FR 49722) and that it would appreciate suggestions for improvement of the Guidelines, (66 FR 49723), these comments address both the "capable of being substantially reproduced" standard and several additional matters.

SUMMARY

GE applauds the general thrust of the Guidelines and agrees with OMB that it is essential that information disseminated by the federal government be of the highest quality. The Guidelines will provide valuable guidance to other agencies in developing and implementing their own information quality guidelines. However, GE believes that the OMB Guidelines are inconsistent with Section 515 in two critical respects and could be improved in several additional respects. GE's comments on the Guidelines are summarized below:

- "Quality" Should be Defined Independently of "Utility," "Objectivity" and "Integrity." The Guidelines' definition of "quality" is inconsistent with Section 515 because it subsumes the separate, explicit statutory mandate to ensure "quality" information into the other statutory requirements regarding "utility," "objectivity" and "integrity." By doing so, the Guidelines fail to clearly require federal agencies to strive to provide excellent, complete, up-to-date and accurate information. **Recommendation.** The Guidelines should include an independent, general definition of "quality" as information that is "excellent, complete, up-to-date and accurate." In addition, the Guidelines should adopt for "influential scientific or statistical information" the definition of "quality" used in the Safe Drinking Water Act ("SDWA") and impose that definition on the specific agency implementing guidelines. OMB should also recommend that the federal agencies consider including in their guidelines specific factors to be used to determine whether "influential scientific or statistical information" meets the SDWA standard.[1]

[1] Such factors might include considerations of reproducibility, peer review, accuracy, precision, method validation, data validation, quality assurance/quality control, relevance of the study method to the study hypothesis, experimental conditions, control of confounding factors and covariates, qualifications and experience of persons collecting data, representativeness of study materials/populations, weight-of-evidence assessment, and appropriateness of statistical methodologies employed.

- Peer Review Should Not Create a Presumption of "Quality". The Guidelines' recommendation that peer reviewed information should "generally be considered of acceptable objectivity" gives too much credit to the benefits of peer review. It is well-known that peer review has not been successful in blocking occasional publication of erroneous – and even fraudulent – research results. More importantly, the peer review process followed by academic journals, while a laudable process that can assist in preventing the publication of seriously flawed research, cannot and does not eliminate the publication of biased or poor quality research. **Recommendation.** The Guidelines should be revised to make peer review just one of several factors that an agency should consider in assessing the objectivity (and quality in general) of original research.

- The "Capable of Being Substantially Reproduced" Provision Should be Clarified. The "capable of being substantially reproduced" provision needs to be modified because it is unclear and, literally interpreted, is inconsistent with scientific principles. The provision should be revised to recognize that, depending on the type of scientific study at issue, there is a some critical aspect of the study that must be reproducible, or repeatable, if the study is to be considered valid. In "hard sciences," such as chemistry, reproducibility of "raw" data should be expected. In other fields, such as epidemiology, where it is not possible to reproduce raw data, reproducibility of study results should be expected. **Recommendation.** First, the Guidelines should be revised to define the term "data" as scientific information in its most simple form, such as physical measurements, read-outs from instruments, test scores, etc., and the term "results" as a higher, or more synthesized, type of information – e.g., trends in data, conclusions that can be drawn from data, statistical associations, etc. Second, the Guidelines should be revised to provide that in situations involving influential scientific or statistical information, data and results must be reproducible where it is theoretically possible for the data to be reproduced and results must be reproducible where data reproducibility is not theoretically possible.

- Additional Quality Standards Should Apply to Agency Recommendations Based on Synthesis of the Results of Scientific or Statistical Studies. In the area of scientific information, the Guidelines should distinguish between agency dissemination of the results of an individual scientific or statistical study, and an agency's evaluation, recommendation or decision based on the agency's analysis and synthesis of a number of scientific or statistical studies. Although the "influential scientific and statistical information" data quality requirements set forth in the Guidelines are applicable to reviews of the individual studies consulted in the course of an agency's assessment, much more is required of an agency's assessment as it brings the force of the agency's power and influence to the conclusions of the evaluation, recommendation or decision. **Recommendation.** Dissemination of an agency evaluation, recommendation or decision based on the agency's analysis and synthesis of a number of scientific or statistical studies should only occur after: (1) the analysis and synthesis has been conducted consistent with the "weight-of-evidence" approach or, if applicable, "causation analysis;" and (2) a full and fair peer review of the weight of evidence/causation analysis has been conducted.

- The "Administrative Correction" Mechanisms Should be Specified in More Detail. The Guidelines are inconsistent with Section 515's mandate that agencies establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency because they:

  - do not require agencies to establish a time period in which the investigation and response must be made;

  - do not require a substantive response; and

  - do not require the agencies to provide a right of appeal from a refusal to correct information that does not comply with the guidelines.

  Recommendation. To properly fulfill OMB's mandate in implementing Section 515 of the Act, these three critical elements of the administrative mechanism should be specified by OMB and brought forward in each specific agency's implementing guidance.

These matters are addressed in turn below:

COMMENTS

A. The Guidelines' Definition of "Quality"

Section 515 of the Act requires OMB to issue Guidelines to the federal agencies requiring the agencies to issue their own guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency . . . " (emphasis added). The underlined words in the quotation were used separately by Congress, indicating that Congress intended that federal agencies ensure and maximize all four of these individual characteristics of information.

The OMB Guidelines, however, define "quality" as "an encompassing term comprising utility, objectivity and integrity." Statements in the preamble to the Guidelines suggest strongly that OMB equates quality with objectivity, utility, and integrity. See 66 FR at 49720 ("OMB defines 'quality' as the encompassing term, of which 'utility,' 'objectivity,' and 'integrity' are the constituents" (emphasis added)).[2] Thus, it appears that the Guidelines do not address what is commonly meant by the term "quality" and define quality information simply as information that: (1) has utility (i.e., is useful); (2) is objective (i.e., was unbiased in collection and is presented in an unbiased fashion); and (3) has integrity (i.e., has not been compromised). The term "quality" means more than that.

[2] See also 66 FR 49721 (equating "quality, utility, objectivity and integrity" with usefulness, whether the disseminated information is presented in an accurate, clear, complete, and unbiased manner, and whether the information has been protected from unauthorized access or revision).

The term "quality" is most commonly used to refer to "degree of excellence" or "degree of conformance to a standard."[3] When used alone – e.g., a "quality automobile" -- the term "quality" typically refers to "inherent or intrinsic excellence of character or type."[4] When Congress required that agency guidelines be adopted to ensure and maximize "quality," it intended that the federal agencies strive to provide excellent, complete, up-to-date and accurate information. The OMB Guidelines, by limiting "quality" to "utility, objectivity and integrity," do not achieve this result.

A simple example should suffice to illustrate that information could have utility, objectivity and integrity and still not be of high quality. Assume that a federal agency decided to publish data on astronomical distances and that, for the mean distance from the earth to the moon, the agency relied on pre-1960 measurements. Pre-1960 measurements of this distance are less accurate and precise than measurements made later using advanced optics and computers. Under the OMB Guidelines, dissemination of the distance from the earth to the moon using pre-1960 measurements would apparently meet the information quality standards so long as the published value was objectively measured, had not been tampered with, and was accurate enough to be useful for most purposes. However, the quality of the value would not have been "ensured and maximized" because the published value was not based on the most accurate and up-to-date information.

A recent "real world" example of a federal agency's failure to use quality science is Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000). In that case, EPA was aware that the most up-to-date science showed that chloroform is a threshold carcinogen – i.e., it is not expected to cause cancer below a certain threshold dose. Ignoring this fact, EPA adopted a Maximum Contaminant Level Goal for chloroform of zero. The Court vacated the MCLG because the Agency had not use the "best available science."

It is noteworthy that the preamble to the Guidelines touches on the meaning of "quality" as that term is used in connection with scientific studies and information about risks of adverse health effects by referring to the standards of the Safe Drinking Water Act ("SDWA"). The preamble notes that the SDWA requires that regulations promulgated under the SDWA be based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and "data collected by accepted methods." 66 FR 49719. Moreover, the SDWA provides that in documents made available to the public to support regulatory decisions, EPA must specify, among other things, "each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty" and "peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the

[3] Webster's Third New International Dictionary of the English Language (unabridged, 1993).

[4] Id.

methodology used to reconcile inconsistencies in the scientific data." 42 U.S.C. 300g-1(b)(3)(B). However, the Guidelines do not adopt these standards – or similar standards – to define what scientific "quality" means. Rather, OMB merely "urges" each agency in developing its Guidelines to evaluate "whether adopting or adapting these basic Congressional standards would be appropriate for judging the quality of disseminated scientific or statistical information." Id. GE believes that, by failing to define "quality" for "influential scientific or statistical information," OMB is abrogating its responsibility to develop guidelines under Section 515 that "ensure and maximize the quality" of information disseminated by federal agencies.

Recommendation. At a minimum, the Guidelines should adopt the SDWA statutory language defining "quality" for the category of "influential scientific and statistical information," and impose these elements as a separate requirement to be included in the individual Agency guidelines. OMB should also recommend that the federal agencies consider including in their guidelines specific factors to be used to determine whether "influential scientific or statistical information" meets the SDWA standard. Such factors might include:

- Whether the information is the best available, peer reviewed science.
- Whether the most accurate and precise methods available were used to collect the information.
- Whether the method of measurement was validated.
- Whether the data were validated.
- Whether quality assurance/quality control techniques were applied.
- Whether the method used will produce data that are relevant to evaluating the hypothesis of the study.
- Whether experimental conditions were carefully controlled.
- Whether confounding factors were eliminated or successfully controlled.
- Whether covariates were successfully controlled.
- Whether the degree and source of variation in measurement were determined.
- Whether the data were collected by individuals with the qualifications and experience required given the nature of the data.
- Whether study materials/populations were representative given the conclusions drawn from the study.
- Whether appropriate statistical methodologies were employed.

- Whether weight-of-evidence analysis was applied to the information.

B. The Guidelines' Definition of "Objectivity"

The Guidelines note correctly that "objectivity" involves two distinct elements: presentation and substance. GE believes that the Guidelines should be revised with respect to assessing substantive objectivity.

The Guidelines state appropriately that substantive objectivity involves ensuring accurate, reliable, and unbiased information and that, in the scientific context, data should be generated and results analyzed using sound statistical and research methods. However, GE disagrees with the statements in the Guidelines that results subject to formal, independent, and external peer review "can generally be considered of acceptable quality," and that in cases involving influential scientific information, "the results must be capable of being substantially reproduced, if the original or supporting data are independently analyzed using the same models."

1. Peer Review

GE disagrees with the Guidelines' recommendation that peer reviewed information should "generally be considered of acceptable quality" and suggests that the Guidelines be revised to make peer review just one of several factors that an agency should consider in assessing the objectivity (and quality in general) of original research. It is well-known that peer review has not been successful in blocking occasional publication of erroneous – and even fraudulent – research results.

More importantly, the peer review process followed by academic journals, while a laudable process that can assist in preventing the publication of seriously flawed research, cannot and does not eliminate the publication of biased or poor quality research. As the National Research Council ("NRC") has found:

> Peer review cannot substitute for technically competent work in the development of a product. It is not a foolproof remedy for poor work. Although peer review can be a valuable tool for improving a work product, it cannot be relied upon to ensure excellence in a product that is seriously lacking in technical merit when it enters peer review.

Strengthening Science at EPA, NRC (2000), at 101.

There are at least three factors that limit the ability of peer review to insure quality:

- Peer reviewers only occasionally ask for and/or are provided the data underlying complex studies. Without review of raw data, a peer reviewer can never be sure that the conclusions of a study are correct

- Reviewers' comments are at most recommendations that need not be heeded by the author or the journal editor. As the NRC has stated:

> Peer review is not quality assurance or quality control per se. It is essentially advisory, not controlling. Although it can be an important guide and aid to those responsible for ensuring quality, the essence of peer review is to criticize constructively, not to decide. . . . The benefits of peer review are diminished if the integrity of the peer-review process is compromised or if the criticisms and suggestions received from independent peer reviewers are to some degree ignored or taken lightly by decision-makers who may be more interested in meeting a deadline or producing a desired answer than in judging or enhancing technical merit.

Strengthening Science at EPA, NRC (2000), at 100.

- The quality of studies published by different journals varies; some journals enjoy little respect due to their low standards of quality control. Making peer review the sole "gatekeeper" in determining whether information can be disseminated by federal agencies would increase the incentive for authors of low quality studies to seek out "journals of last resort" and would potentially create flight from quality journals.

Thus, although peer review is undoubtedly important in improving the quality of academic papers, it is not appropriate that any presumption regarding quality be attached to research findings that have undergone peer review.

Recommendation. The Guidelines should be revised to state that the fact that research findings have been peer reviewed is just one factor that an agency should consider in judging research quality.

2. The "Capable of Being Substantially Reproduced" Provision

GE believes strongly that the Guidelines need significant revision with respect to the "capable of being substantially reproduced" provision. First of all, reproducibility should be discussed as a matter of quality, not objectivity. As a general matter, if data or study results cannot be reproduced or repeated, that fact bears on the quality of the data. It may or may not bear on the objectivity of the scientist who published the data.

Second, the "capable of being substantially reproduced" provision needs to be modified for clarity and consistency with scientific principles. The Guidelines' provisions regarding reproducibility are very difficult to understand and, literally interpreted, do not make sense. The Guidelines first define "capable of being reproduced" as meaning "that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision" (emphasis added). The Guidelines then provide that "[i]n those situations involving influential scientific or statistical information, results must be capable of being substantially reproduced, if the original or supporting data are independently analyzed using the same models" (emphasis added). The Guidelines go on to state that

"[r]eproducibility does not mean that the original or supporting data have to be capable of being replicated through new experiments, samples or tests" (emphasis added). On its face, the above-quoted language seems to say that: (a) it is not important whether hard data can be reproduced; and (b) all that matters is whether the conclusions or interpretations of raw data can be reproduced. This is incorrect because it is universally accepted that data reproducibility is one of the most fundamental tenets of the scientific method.

Given this, it seems likely that the above-quoted language from the Guidelines resulted from inartful drafting, not from any fundamental misunderstanding. The drafting problem likely stems primarily from: (1) the use of the words "data" and "results" without definition; and (2) the failure to recognize that, depending on the type of scientific study at issue, there are differences in what elements of the study can be reproduced and, therefore, what should be reproducible.

In the following discussion, we use the word "data" to mean what is often referred to as "raw data" -- scientific information in its most simple form, such as physical measurements, read-outs from instruments, test scores, etc. We use the term "results" to refer to a higher, or more synthesized, type of information – e.g., trends in data, conclusions that can be drawn from data, statistical associations, etc.

In some areas of scientific research, a study's data must be precisely reproducible if the results of a study are to be believed. For example, if a chemist measures the boiling point of a substance at sea level and then published his or her procedures and data (the boiling point), any other qualified chemist should be able to follow the described procedures and obtain the same data. If this type of data are precisely reproducible, they are considered valid; if not, they are very seriously questioned.[5] Precise replication of data is expected in a wide spectrum of scientific pursuits, from astrophysics to microbiology.

In other areas, however, reproduction of data, although expected, is judged using somewhat looser standards. For example, in toxicology, one expects that two scientists each exposing 20 rats of the same species and strain to the same dose of the same chemical will obtain similar, though not necessarily identical, data. Given the many potential covariables in even the most straightforward toxicological study, one would not expect the scientists to obtain identical data. But if one scientist found 10 of 20 rats affected and the other found 8 of 20 rats affected, we would nevertheless say that the scientists had reproduced each other's data.

Conversely, in some sciences, such as epidemiology, reproduction of data from a study is not possible, even in theory. For example, assume that an epidemiologist measured lead concentrations in the umbilical cord blood of a cohort of children at birth, gave the cohort IQ tests at age 10, determined that there was an association between higher lead levels and lower test scores, and then published the data and the results. The data clearly can

[5] For example, we do not believe cold fusion exists because the original study data could not be reproduced.

not be reproduced – simply because time has passed, it is no longer possible to again sample the children's umbilical cord blood at the time of birth and to give them IQ tests at age 10. Nevertheless, we reasonably expect that the results of the study should be reproducible, or repeatable, with an acceptable degree of precision. That is, if another scientist defined a similar cohort, used the same analytical method to measure umbilical cord blood lead concentrations, and gave the children the same test at the same age, we would expect him or her to find an association between higher lead levels and lower test scores. If such an association was not found, this would lead us to question the results of both studies. If the study was repeated several more times using different cohorts, and if the additional studies failed to confirm the originally reported association between higher lead levels and lower test scores, we would ultimately decide that the results of the original study were incorrect.

Recommendation. The Guidelines should be revised to define the terms "data" as scientific information in its most simple form, such as physical measurements, read-outs from instruments, test scores, etc., and "results" as a higher, or more synthesized, type of information – e.g., trends in data, conclusions that can be drawn from data, statistical associations, etc. The Guidelines should further state that in situations involving influential scientific or statistical information, data and results must be reproducible where it is theoretically possible for the data to be reproduced and results must be reproducible where data reproducibility is not theoretically possible.[6] Note that these statements do not require that the data or results have been reproduced. Nor does it require an agency to reproduce data or results. It simply requires that data and/or results be of a type that are capable of being reproduced and that it has not been shown that the data or results are, in fact, not reproducible.

D. The Need for Different Information Quality Standards for Different Types of Information

The preamble to the Guidelines recognize that different types of information will be subject to the Guidelines, including statistical data collected by the Census Bureau and the Bureau of Labor Statistics, FAA air travel advisories, self-reported data such as EPA's Toxic Release Inventory information, and information about health, safety, and environmental risks. 66 FR 49718-19. The preamble also indicates, correctly, that certain information that has not been authored by the agency and that does not reflect the agency's views (such as information in books maintained in an agency library and corporations' SEC filings) should not be subject to the Guidelines. Id. at 49720. However, other than recognizing that somewhat more stringent standards should apply to "influential scientific and statistical information" and that the appropriate procedures for

[6] Note that this requirement assumes, in cases where it is theoretically impossible to reproduce data and therefore only results must be reproducible, that reproducibility is demonstrated by conduct of a new study that produces its own data and results. We mention this issue because the Guidelines make the statement that "results must be capable of being substantially reproduced, if the original or supporting data are independently analyzed using the same models." Although we agree with this statement, reproducibility is not demonstrated by re-analysis of data. Reproducibility is demonstrated by generation and analysis of new data.

correction of information may depend on the importance of the information, the Guidelines do not reflect the fact that different types of information quality guidelines should be applicable to different types of information.

In the area of scientific information, the Guidelines do not differentiate between agency dissemination of the results of an individual scientific study and an agency evaluation, recommendation or decision based on the agency's analysis and synthesis of a number of scientific studies, some of which may present disparate results. For example, EPA and the Agency for Toxic Substances and Disease Registry ("ATSDR") both conduct reviews of the toxicology of various chemicals and characterize the risks that exposure to such chemicals may present. These endeavors typically involve reviewing the results of numerous animal bioassays and human clinical and epidemiological studies. Based on these reviews, both agencies disseminate information to the public in the form of the agencies' toxicological assessments of chemicals, opinions regarding whether certain chemicals may cause cancer or non-cancer diseases in humans, and numerical estimates of the cancer or non-cancer toxicity of particular chemicals.

This information is extremely influential because it is used by EPA and state environmental agencies for several purposes, including issuing air, waste and water pollution regulations and developing clean-up requirements for contaminated sites. Such assessments also go beyond providing mere information since they may be cited by toxic tort plaintiffs or other litigants and potentially bring the force of the agency's scientific imprimatur into numerous legal proceedings. As such, a higher standard of care regarding the quality of such information is required before it should be disseminated.

Although the scientific data quality requirements set forth in the guidance are applicable to reviews of the individual studies consulted in the course of a toxicological assessment, much more is required if a toxicological assessment is to result in the dissemination of quality information in the form of cancer and non-cancer assessments and numerical estimates of toxicity. The same is true of other agency evaluations, recommendations or decisions based on the agency's analysis and synthesis of a number of scientific studies.

Recommendation. Dissemination of information based on an agency's analysis and synthesis of a number of scientific studies should only occur after: (1) the analysis and synthesis has been conducted consistent with the "weight-of-evidence" approach and, in appropriate cases, "causation analysis" principles; and (2) a full and fair peer review of the weight of evidence has been conducted.

1. Weight-of-Evidence Analysis

Synthesizing the results of a number of scientific studies whose findings are not entirely consistent requires application of the weight-of-evidence approach. The primary benefits of the weight-of-evidence approach are that it assists the decision maker in organizing and sorting through scientific findings that may appear to conflict and provides a reasoned and rational framework for both making and presenting decisions. The weight-of-evidence approach involves careful and thorough review of study methodologies and

results, as well as assessment of the relative weights that should be given to the results of individual studies or groups of studies. The importance that should be given to a particular study depends both on the quality of the study and its relevance to the issue being analyzed. Quality is assessed using principles that have been discussed above and factors such as method accuracy, precision, and validation, quality assurance/quality control, control of experimental conditions, confounding factors and covariates, representativeness of study materials/populations, and appropriateness of statistical methodologies employed. Relevance of a study is related to the extent to which it addresses the issue under investigation. For example, if an agency was developing standards for paints that may be used by federal contractors to paint steel bridges, a high quality study of the durability of paints applied to locomotives would be given more weight than a high quality study of paints used to coat aluminum coils. Although both studies are relevant, the first is more "on point."

A type of weight-of-evidence assessment, usually referred to as "causation analysis," is of particular utility in determining whether there is likely to be a causal relationship between events or circumstances that have been found to be associated. As EPA has recognized, causation analysis is very useful in determining whether exposure to a particular chemical causes an increased risk of disease.[7] As typically applied, the scientific demonstration of causation requires the observation of a specific effect endpoint and satisfaction of all or most of six fundamental "causation criteria" – strength of association, existence of a dose-response relationship, consistency of association, specificity of association, biological plausibility, and existence of a temporally correct

[7] EPA endorsed causation assessment in its Proposed Guidelines for Carcinogen Risk Assessment (1996). This document provide a number of explicit recommendations and criteria for evaluating a body of literature in order to establish whether a particular chemical causes a particular effect:

> Analyzing the contribution of evidence from a body of human data requires examining available studies and weighing them in the context of well-accepted criteria for causation. A judgment is made about how closely they satisfy these criteria, individually and jointly, and how far they deviate from them. Existence of temporal relationships, consistent results in independent studies, strong association, reliable exposure data, presence of dose-related responses, freedom from biases and confounding factors, and high level of statistical significance are among the factors leading to increased confidence in a conclusion of causality. Generally, the weight of human evidence increases with the number of adequate studies that show comparable results on populations exposed to the same agent under different conditions. The analysis takes into account all studies of high quality, whether showing positive associations or null results, or even protective effects. In weighing positive studies against null studies, possible reasons for inconsistent results should be sought, and results of studies that are judged to be of high quality are given more weight than those from studies judged to be methodologically less sound. Generally, no single factor is determinative. For example, the strength of association is one of the causal criteria. A strong association (i.e., a large relative risk) is more likely to indicate causality than a weak association. However, finding of a large excess risk in a single study must be balanced against the lack of consistency as reflected by null results from other equally well designed and well conducted studies. In this situation, the positive association of a single study may either suggest the presence of chance, bias or confounding, or reflect different exposure conditions. On the other hand, evidence of weak but consistent associations across several studies suggests either causality or the same confounder may be operating in all of these studies.

association (Hill, 1965; Evans, 1976; Hackney and Linn, 1979; Doll, 1984; Guidotti and Goldsmith, 1986; Mausner and Kramer, 1985; Monson, 1988; Hernberg, 1992). Causation or lack of causation is established by the weight-of-evidence and the extent to which the criteria are satisfied by the available data on a particular outcome.

As OMB has recognized (66 FR 49719; J.D. Graham, Memorandum for the President's Management Council (Sept. 20, 2001), at 2-3), Congress has also endorsed causation analysis in assessing the risks of chemicals. As noted in the Guidelines, the SDWA provides that in documents made available to the public to support regulatory decisions, EPA must specify, among other things,

> (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and
>
> (v) peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. 300g-1(b)(3)(B). This language, while not specifically referring to causation analysis or weight-of-evidence assessment, fully embodies the concept underlying these approaches. First, it requires that EPA acknowledge uncertainties and conflicts in study results. Second, it states that EPA must take into account <u>all</u> studies – not just ones favoring a particular position – and reconcile the differences among study results. This is the essence of weight-of-evidence assessment and causation assessment.

If information to be disseminated by agencies is to be of the highest quality, general information quality guidelines will not suffice for information based on agency analysis and synthesis of a number of scientific studies. The Guidelines should require that such assessments be conducted consistent with the "weight-of-evidence" approach and, in appropriate cases, "causation analysis" principles.

2. *Full and Fair Peer Review*

Before dissemination of an agency's recommendation or decision based on the agency's assessment and synthesis of a number of scientific studies, that assessment should be subject to full and fair peer review. OMB has already recognized this need, stating that economically significant and major rulemakings should be subject to independent and "open and rigorous" peer review. J.D. Graham, Memorandum for the President's Management Council (Sept. 20, 2001), at 3. The OMB Guidelines should follow this lead and require full and fair peer review of complex and important agency decisions requiring analysis and synthesis of large numbers of studies or bodies of data.

There are several sources that OMB can rely on to define appropriate peer review procedures (Lock, 1985; Rennie, 1990; Rennie and Flanagin, 1994, 1998; NRC, 1998; EPA, 1998). Guidance on some of the pitfalls in implementing peer review can be found in numerous sources, including NRC (2000) and the sources cited therein. OMB should, however, stress that peer reviews be "full" and "fair" and viewed as an important part of

the decision making process, rather than a bureaucratic requirement. Reviews of the EPA peer review process by the NRC and the EPA Science Advisory Board ("SAB") are instructive in this regard. Although EPA has endorsed peer review and has developed extensive peer review guidance, the NRC and the SAB have found that EPA has failed to subject to peer review certain important issues and assessments and has used methods that do not assure that peer reviews are unbiased. SAB (1999) recently found that EPA peer review charges sometimes "ask only very selected questions, sometimes dodging the crucial scientific issues,"[8] and SAB (2001) reported that some very important EPA products have not been peer reviewed, including "the technical resources documents for the MACT standards, the TRI lead rule, and the individual source category residual risk assessments for all but a single source category."[9] Moreover, SAB (1999) and the NRC (2000) recently stated serious concerns regarding "potential conflict of interest on the part of peer-review leaders."[10]

GE therefore recommends that the Guidelines be amended to require the federal agencies to adopt procedures that afford full and fair peer review and require that these procedures be used prior to dissemination of agency evaluations, recommendations or decisions based on the agency's analysis and synthesis of multiple scientific studies.

E. Mechanisms Providing for Correction of Disseminated Information

Section 515 requires that the OMB Guidelines require each agency to issue Guidelines that "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency . . . ."
The provisions in the proposed OMB Guidelines fall far short of what Congress required when it instructed OMB to issue guidelines requiring "administrative mechanisms

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[8] SAB (1999), at 14.

[9] SAB (2001) (cover letter).

[10] NRC (2000), at 19-20. See also SAB (1999), at 11. NRC (2000) stated as follows:

> EPA's SAB has expressed concern about potential conflict of interest on the part of peer-review leaders — individuals assigned to manage reviews of agency work products — because current agency policy allows the same individual to be a project manager for the development of a particular work product and the peer-review leader for the same work product. The SAB noted that such a manager might have a special interest in the outcome of the review and might therefore be unable to ensure the essential degree of independence . . . .
>
> Our committee shares the SAB's concern about the potential for conflicts of interest of EPA peer-review leaders and decision-makers. Despite good intentions, and even if the current policy works well much of the time, some of these individuals, under pressure to meet a deadline or implement a regulatory policy, might be tempted to compromise the integrity of the peer-review process for some work products by making convenient or improper decisions on the form of peer review, the selection of reviewers, the specification of charges to the reviewers, or the responses to reviewers' comments.

allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency." The language chosen by Congress – requiring "administrative mechanisms" allowing persons to "obtain" correction of erroneous information – suggests strongly that Congress wanted OMB to require the federal agencies to adopt procedures that provide affected persons a real opportunity to show an agency that it had made a mistake, require the agency to investigate the claim seriously, complete that investigation in a timely manner, respond substantively to the affected person, and make a correction if warranted by the results of the investigation. Moreover, Congress' command that the Guidelines allow an affected person to "seek and obtain" a correction suggest that the procedures must provide some mechanism for an affected person to compel the agency to make a correction when a mistake has been made.

The Guidelines should require the Federal Agencies to:

- specify the period in which the investigation and response should be made;
- provide a substantive response; and
- specify the appeal rights or other mechanism that might be used to compel an agency to correct incorrect information.

Recommendation. The Guidelines are unresponsive to the requirements of Section 515 relating to mechanisms providing for correction of disseminated information, and should be revised to address the three (3) specific deficiencies noted above.

CONCLUSION

GE appreciates OMB's efforts in developing the information quality Guidelines, as well as OMB's openness to suggestions for improvement of the Guidelines. The recommendations set forth in GE's comments do not contain any new or radical ideas – they simply ask that OMB take the opportunity provided by Section 515 to mandate that all federal agencies apply well-known and widely accepted concepts of "the best science" when generating and disseminating "influential scientific and statistical information". GE urges OMB to consider these comments carefully and to continue its efforts to improve the quality of work performed by the federal agencies on behalf of the public.

REFERENCES

Doll, R. 1984. Occupational cancer: Problems in interpreting human evidence. Ann.Occup.Hyg. 28, 291-305.

EPA. 1998. EPA Science Policy Council Handbook: Peer Review (EPA 100-B-98-001).

Evans, A. S. 1976. Causation and disease: The Henle-Koch postulates revisited. The Yale Journal of Biology and Medicine 49, 175-195.

Fein,G.G., Jacobson,J.L., Jacobson,S.W., Schwartz,P.M., and Dowler,J.K. 1984. Prenatal exposure to polychlorinated biphenyls: effects on birth size and gestational age. J. Pediat., 105, 315-320

Hackney, J. D. and Linn, W. S. 1979. Koch's postulates updated: a potentially useful application to laboratory research and policy analysis in environmental toxicology. Am.Rev.Respir.Dis. 119, 849-852.

Hernberg,S. 1992. Supporting evidence for cause-effect inferences. In Introduction to Occupational Epidemiology. pp. 220-222.Lewis Publishers, Inc., Chelsea, MI

Hill, A. B. 1965. The environment and disease: Association or causation? Proc.R.Soc.Med. 58, 295-300.

Jacobson, S. W., Jacobson, J. L., Schwartz, P. M., and Fein, G. G. (1983). Intrauterine exposure of human newborns to PCBs: Measures of exposure. In PCBs: Human and Environmental Hazards (F. M. D'Itri, and M. Kamrin, Eds.), pp. 311-343. Butterworth, Boston.

Jacobson, J. L., Schwartz, P. M., Fein, G. G., and Dowler, J. K. 1984. Prenatal exposure to an environmental toxin: A test of the multiple effects model. Dev. Psychobiol. 20, 523-532.

Jacobson, S. W., Fein, G. G., Jacobson, J. L., Schwartz, P. M., and Dowler, J. K. 1985. The effect of intrauterine PCB exposure on visual recognition memory. Child Dev. 56, 853-860.

Jacobson, J. L., and Jacobson, S. W. 1996. Dose-response in perinatal exposure to polychlorinated biphenyls (PCBs): the Michigan and North Carolina cohort studies. Toxicology And Industrial Health 12, 435-445.

Guidotti, T. and Goldsmith, D. 1986. Occupational Cancer. American Family Physician 34, 146-152.

Lock, S., ed. 1985. A Difficult Balance: Editorial Peer Review In Medicine. Philadelphia: ISI Press.

Monson, R. 1988. Occupational Epidemiology, CRC Press, Boca Raton, Florida.

Mausner,J.S. and Kramer,S. 1985. Epidemiologic study cycles. In Mausner & Bahn Epidemiology-An introductory text. pp. 154-194.W.B.Saunders Co., Philadelphia

NRC. 2000. Strengthening Science at the U.S. Environmental Protection Agency. Washington, DC: National Academy Press.

NRC. 1998. Peer Review in Environmental Technology Developmental Programs. Washington, DC: National Academy Press.

Rennie, D., ed. 1990. Guarding the guardians, research on editorial peer review: Selected Proceedings from the First International Congress on Peer Review in Biomedical Publication. JAMA 263(10).

Rennie, D., and A. Flanagin, eds. 1994. The Second International Congress on Peer Review in Biomedical Publication. JAMA 272(2).

SAB. 199. An SAB Report: Review of the Peer Review Program of the Environmental Protection Agency (November).

SAB. 2001. Implementation of the Environmental Protection Agency's Peer Review Program: An SAB Review (Draft, July 11).

Bradford Hill Criteria for Causality

A causal interpretation is enhanced for studies to the extent that they meet the following criteria in the light of all other information on the agent being assessed. None of the criteria is conclusive by itself, and the only criterion that is essential is the temporal relationship.

Temporal relationship: The development of cancers requires certain latency periods, and while latency periods vary, existence of such periods is generally acknowledged. Thus, the disease has to occur within a biologically reasonable time after initial exposure. This feature must be present if causality is to be considered.

Consistency: Associations occur in several independent studies of a similar exposure in different populations, or associations occur consistently for different subgroups in the same study. This feature usually constitutes strong evidence for a causal interpretation when the same bias or confounding is not also duplicated across studies.

Magnitude of the association: A causal relationship is more credible when the risk estimate is large and precise (narrow confidence intervals).

Biological gradient: The risk ratio (i.e., the ratio of the risk of disease or death among the exposed to the risk of the unexposed) increases with increasing exposure or dose. Statistical significance is important, and a strong dose-response relationship across several categories of exposure, latency, and duration is supportive for causality, given that confounding is unlikely to be correlated with exposure. The absence of a dose-response relationship, however, is not by itself evidence against a causal relationship.

Specificity of the association: The likelihood of a causal interpretation is increased if an exposure produces a specific effect (one or more tumor types also found in other studies) or if a given effect has a unique exposure.

Biological plausibility: The association makes sense in terms of biological knowledge. Information is considered from animal toxicology, toxicokinetics, structure-activity relationship analysis, and short-term studies of the agent's influence on events in the carcinogenic process considered.

Coherence: The cause-and-effect interpretation is in logical agreement with what is known about the natural history and biology of the disease, i.e., the entire body of knowledge about the agent.